FILED UNDER SEAL

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PLAINTIFFS UNDER SEAL	)	**Civil Action No. 09-4653 (SRC)**
v.	)	**FILED UNDER SEAL**
DEFENDANTS UNDER SEAL	)	**JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS 31 U.S.C. § 3729, ET SEQ.

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* STEPHEN ELLIOTT and JAMES LUNDSTROM, on behalf of the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN, and THE DISTRICT OF COLUMBIA	
Plaintiff,	
v.	
BRISTOL-MYERS SQUIBB COMPANY, APOTHECON, INC., PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC.,	**FILED UNDER SEAL**
Defendants	**JURY TRIAL DEMANDED**

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FIRST AMENDED COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS, 31 U.S.C. § 3729, *ET SEQ.* AND STATE LAW COUNTERPARTS

This is an action brought on behalf of the United States of America by James Lundstrom and Stephen Elliott, by and through their attorneys, against Defendants pursuant to the qui tam provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.*; the California False Claims Act, CAL. GOV'T CODE § 12650 (Deering 2000), *et seq.*; the Colorado Medicaid False Claims Act, COLO. REV. STAT. § 25.5-4-304 (2010) *et seq.*; the Connecticut False Claims Act, 2009 CONN. PUB. ACTS NO. 09-5 (Sept. Spec. Sess.), *et seq.*; the Delaware False Claims and Reporting Act, DEL. CODE ANN. Tit. 6, § 1201 (2000), *et seq.*; the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.13 (2000), *et seq.;* the Florida False Claims Act, FLA. STAT. 68-081 (2000), *et seq.*; the Georgia False Medicaid Claims Act, GA. CODE ANN.§ 49-4-168 (2007), *et seq.*; the Hawaii False Claims Act. HAW. REV. STAT. § 661-22, (2006) *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. ANN. § 175/1 (2000), *et seq.*; the Indiana False Claims and Whistleblower Protection Act, INDIANA CODE § 5-11-5.5, (2007) *et seq.*, the Louisiana Medical Assistance Programs Integrity, LA. REV. STAT. ANN. § 46.439.1 (2006), *et seq.;* the Massachusetts False Claims Act, MASS. ANN. LAWS ch. 12, § 5(A), (2007) *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.601, (2007) *et seq.* (2007); the Minnesota False Claims Act, MINN. STAT. § 15C.01 *et seq.*; the Montana False Claims Act, MONT. CODE ANN. § 17-8-401 (2005), *et seq.*; the Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. § 357.010 (1999), *et seq.*; the New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-b (2005), *et seq.*; the New Jersey False Claims Act, N.J. STAT. ANN. § 265 (2007); the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-1 (2007), *et seq.*; the New York False Claims Act, N.Y. CLS ST. FIN. § 190.6. (2007), *et seq.*; the North

Carolina False Claims Act, N.C. GEN. STAT. § 1-605, *et. seq.*; the Oklahoma Medicaid False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*; the Rhode Island False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*; the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-181(c) (2006), *et seq.*; the TEX. HUM. RES. CODE § 36.001 (2006), *et seq.*; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. § 8.01-216.1 (2006), *et seq.*, and the Wisconsin False Claims for Medical Assistance Act, WIS. STAT. § 20.931 (2007), *et seq.*, ("State *qui tam* statutes" or "*Qui Tam* States").

1. This is an action to recover damages and civil penalties on behalf of the United States of America and twenty-seven states (collectively the "Government") arising from false statements and claims made and caused to be made by the Defendants, their agents and, employees in violation of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.* as amended ("the FCA") and twenty-seven parallel state statutes (collectively "the State False Claims Acts" or "State FCAs"). The false and fraudulent claims described herein are based on Defendants violations of the Federal Food Drug and Cosmetic Act, 21 U.S.C. §§ 331(z), 333(a)(1)-(2), 360aaa, by promoting "off-label" -- *i.e.,* unapproved use of Megace® and Megace ES®. The statutory violations have led to the submission of false and fraudulent claims against state and federal Government health insurance programs, as defined and described more fully below, in violation of the State and Federal False Claims Acts.

I. JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345. The Court has original jurisdiction of the State law claims pursuant to 31 U.S.C. § 3732(b) because this action is brought under State laws

for the recovery of funds paid by the *Qui Tam* States, and arises from the same transaction or occurrence brought on behalf of the United States under 31 U.S.C. § 3730.

3. This Court has personal jurisdiction over the Defendants because, among other things, Defendants transact business in this District, and engaged in wrongdoing in this District.

4. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and (c). Defendants principal place of business is located within this District, and acts proscribed by 31 U.S.C. § 3729 occurred in this District.

5. The causes of action alleged herein are timely brought because, among other things, of efforts by the Defendants to conceal from the United States and the *Qui Tam* States their wrongdoing in connection with the allegations made herein.

II. PARTIES

A. RELATOR JAMES LUNDSTROM

6. Relator James Lundstrom ("Relator Lundstrom") is a resident of Tulsa, Oklahoma. Relator Lundstrom was employed as an Area Business Manager ("ABM") at Defendant Par from June 2005 until April 2009, when he was terminated. At all times when he was employed at Par, he promoted Megace ES® in Oklahoma, Arkansas, Missouri and Kansas to a call file of physicians prepared by his employer, which included Radiation Oncologists, Oncology/Hematology Clinics, Teaching Hospitals, Specialists, Nursing Homes and Long-Term Care Facilities, and Geriatric Specialists. He ranked in the Top 10% U.S. Sales Force 2005; ranked Top 20% in 2007-2008; was the winner of Quarterly Market Share Growth Contest 2006; ranked #1 Nationally in quarter over quarter volume 2007; and ranked #1 Nationally in Market Share Growth 2007.

7. Relator Lundstrom is the original source of the Fraudulent Marketing Scheme allegations in this Complaint against Defendant Par, and the allegations in the Fraudulent Marketing Scheme are not based upon publicly disclosed information. He has provided the Government with information prior to the filing of this Complaint in accordance with 31 U.S.C. § 3730(b)(2).

8. Relator Lundstrom voluntarily provided the non-public information alleged herein to the Government prior to filing this action. Accordingly, Relator Lundstrom is an "original source" of the non-public information alleged in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

B. RELATOR STEPHEN ELLIOTT

9. Relator Stephen Elliott ("Relator Elliott") is a resident of Olmsted Falls, Ohio. Relator Elliott was employed as an immunology sales representative of Defendant BMS from June 1997 through January 2002. He was responsible for the sale, business management and clinical communications for HIV/AIDS anti-retroviral drug business in Ohio, Southern Michigan and Western Pennsylvania. Among his responsibilities was sales of Defendant BMS's Megace® to long-term care facilities and geriatric market where he focused on off-label promotion of Megace® for use to treat elderly wasting syndrome reversal. While employed at Defendant BMS, he was one of the top immunology sales representatives, winning the Megace® Achievement Award in 2000 and 2001, the Videx® Achievement Award in 1998, 2000, and 2001, the Best Performers Award, 2001. He also served as a trainer for the Defendant Apothecon sales force. He was the recipient of four "spot awards," and two "Awards For Excellence."

10. Relator Elliott is the original source of the Fraudulent Marketing Scheme allegations in this Complaint against Defendant BMS, and the allegations in the Fraudulent Marketing Scheme are not based upon publicly disclosed information. He has provided the Government with information prior to the filing of this Complaint in accordance with 31 U.S.C. § 3730(b)(2).

11. Relator Elliott voluntarily provided the non-public information alleged herein to the Government prior to filing this action. Accordingly, Relator Elliott is an "original source" of the non-public information alleged in this Complaint within the meaning of 31 U.S.C. § 3730(e)(4)(A) and (B).

C. DEFENDANT BRISTOL-MYERS SQUIBB COMPANY ("BMS")

12. Defendant Bristol-Myers Squibb Company ("BMS") is a Delaware corporation with its principal corporate offices at 345 Park Avenue, New York, New York. At all times material hereto BMS marketed and sold a range of brand pharmaceuticals and consumer medicines, including the drug Megace®, in Pennsylvania and throughout the United States, including within this judicial district.

13. Defendant Apothecon, Inc. ("Apothecon") is a Delaware corporation with its principal place of business located in Princeton, New Jersey. Apothecon is a subsidiary of Defendant BMS, specializing in small to mid-size niche brand and generic products. Collectively, herein Defendants BMS and Apothecon are referred to as "Defendant BMS."

14. Defendant BMS, at all times material hereto, manufactured, marketed, and sold prescription drug products, including Megace®, paid or reimbursed by various Government programs, including health benefit carriers offering benefits under the Federal Employees Health Benefits ("FEHB") program under a prime contract with the Blue Cross Blue Association

("BCBSA"), the Health Insurance Program for the Elderly and Disabled, more commonly referred to as the Medicare Program, 42 U.S.C. § 1395, *et seq.* via Medicare Defendant Part C, also known as Medicare+Choice, patients covered by Medicare Defendant Part D, the Indian Health Service, Medicaid, the Mail Handler's Health Benefit Plan ("MHHBP"), the U.S. Secret Service Employees Health Association ("SSEH") Health Benefit Plan, the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS," now known as "TRICARE"), the Veteran's Health Administration ("VHA") and numerous state health plans, including Medicaid (collectively, the "Government Programs").

15. At all times material hereto, Defendant BMS employed as many as 200 immunology sales representatives/sales managers located across the United States, including in this district, whose function it was to promote, market or otherwise sell Defendant BMS's immunology drugs, including its drug Megace®.

D. DEFENDANT PAR PHARMACEUTICAL COMPANIES, INC. ("PAR")

16. Defendant Par Pharmaceutical Companies, Inc., together with its affiliates, including its brand product division Strativa Pharmaceuticals ("Defendant Par") is a publicly traded, for-profit company, incorporated in Delaware and with its principal place of business located at 300 Tice Boulevard, Woodcliff Lake, New Jersey. Defendant Par is engaged in the business of, among other things, developing, manufacturing, marketing, and distributing drug products. Defendant Par operates primarily through its wholly owned subsidiary, Par Pharmaceutical, Inc., in two business segments, for the development, manufacture and distribution of generic pharmaceuticals and branded pharmaceuticals in the United States. In 2007, Defendant Par began operating the brand pharmaceutical segment under the name Strativa Pharmaceuticals.

17. Defendant Par manufactures, markets, and sells prescription drug products, including Megace ES® and megestrol acetate, paid or reimbursed by various Government programs, including health benefit carriers offering benefits under the FEHB program under a prime contract with the BCBSA, the Medicare Program, 42 U.S.C. § 1395, *et seq*. via Medicare Defendant Part C, also known as Medicare+Choice, patients covered by Medicare Defendant Part D, the Indian Health Service, Medicaid, the MHHBP, the U.S. SSEH Health Benefit Plan, TRICARE, the VH and numerous state health plans, including Medicaid.

18. At all times material hereto, Defendant Par employed as many as 100 sales representatives/sales managers located across the United States, including in this district, whose function it was to promote, market or otherwise sell Defendant Par's drugs, including its drug Megace ES®.

III. SUMMARY OF DEFENDANTS' ILLEGAL CONDUCT

A. THE PLAN AND PURPOSE OF THE FRAUDULENT MARKETING SCHEME.

19. It was the plan and purpose of the Defendants' scheme to illegally promote Megace® and Megace ES® for off-label uses, including oncology and for use with geriatric patients, beginning at least as early as 1997, and continuing to the present in order to fraudulently obtain Governmental reimbursement by causing false and fraudulent claims to be submitted for payment in order to maximize Defendant BMS's and Defendant Par's profits.

B. THE MANNER AND MEANS OF EXECUTING THE SCHEME.

20. It was part of the scheme that Defendant BMS and Defendant Par illegally promoted the off-label sales and use of Megace® and Megace ES® in order to obtain reimbursement for non-medically accepted indications and other off-label treatments in order to

maximize profits by making false and fraudulent statements to the public, healthcare providers and the Food and Drug Administration ("FDA").

21. Defendant BMS's and Defendant Par's unlawful promotion of Megace® and Megace ES® involved the unlawful making of false records or statements for the purpose of getting the false records or statements to bring about the Government's payment of false or fraudulent claims.

22. Defendant BMS's and Defendant Par's conduct had a material effect on the Governments' decision to pay for Megace® and Megace ES®. Had the Government known that reimbursements were being made for Megace® and Megace ES® caused by Defendants BMS's and Defendant Par's unlawful promotion, the Government would not have made such reimbursements.

23. It was further part of the scheme that Defendant BMS and Defendant Par attempted to conceal and cover up the off-label marketing of Megace® and Megace ES® by making false statements to the FDA and directing employees to conceal evidence.

24. The promotion of Megace® and Megace ES® involved the unlawful making of a false record or statement for the purpose of getting the false record or statement to bring about the Governments' payment of a false or fraudulent claim.

25. The scheme, described below, is referred to herein as the "Fraudulent Marketing Scheme."

IV. BACKGROUND ON PROMOTING MEGACE® AND MEGACE ES® FOR OFF-LABEL USES.

A. MARKETING OF PRESCRIPTION DRUGS TO HEALTH CARE PROFESSIONALS.

26. Marketing and advertising have been critical to the success of the pharmaceutical industry in the last two decades. Whether via increasingly common direct-to-consumer ("DTC") advertising or one-on-one physician detailing, drug companies spend billions on drug promotion. Gardiner Harris, *Group Urges Ban on Medical Giveaways*, N.Y. Times, April 28, 2008. In 2000, for example, total national prescription drug promotion expenditures totaled more than $15.7 billion. Of that amount, $4.8 billion is spent on drug detailing alone.

27. It is undisputable that expenditures for drug marketing increase sales. Intense pharmaceutical marketing saturates the pharmaceutical industry and appears in many forms—some of which some people would call disguised. To accomplish these goals and raise sales, Defendant BMS and later Defendant Par utilized all the various channels of information through which pharmaceutical companies can market their products to propel Megace® and its follow-on Megace ES®'s brand message. Those channels—today highly susceptible to industry influence—are described below.

28. The most obvious source of information about a medication is its own prescription label. Although a pharmaceutical company must obtain the FDA's approval for its drug's label, the label is the property of the manufacturer, not the FDA. Initially drafted by the manufacturer, labels are then subject to negotiations between the federal agency and the manufacturer. Because the FDA, however, depends solely on drug safety and efficacy information provided by pharmaceutical companies, it cannot object to a label's shortcomings if it never received the data from the manufacturer showing the drug's drawbacks.

B. DRUG MAKER DETAILING OF DOCTORS AND HEALTH CARE PROFESSIONALS.

29. "Detailing" is the one-on-one promotion of drugs to physicians by pharmaceutical sales representatives, usually through regular office visits, free gifts, and friendly advice, when

"drug reps go to doctors' offices to describe the benefits of a specific drug." Daniel Carlat, *Dr. Drug Rep.*, N.Y. Times Mag., Nov. 25, 2007, at 67.

30. Medical detailing is a large field, employing over 90,000 sales representatives, or one detailer for every 4.5 doctors. The vast majority of doctors—eighty-five to ninety percent—do speak with drug detailers, and most consider them and the information they provide helpful and accurate. Drug representatives ostensibly provide useful information for physicians as they address "difficult problems in treating patients." Jonna Perala et al., *Lifetime Prevalence of Psychotic and Bipolar I Disorders in a General Population,* 64 Archives of Gen. Psychiatry 19, 1892 (2007).

31. Drug company-controlled and produced information has great potential to mislead.

C. THE LIMITED ROLE OF THE FDA IN REGULATING OFF-LABEL PROMOTION OF DRUGS.

1. New Drug Approvals By the FDA.

32. Under the Food, Drug, and Cosmetics Act ("FDCA"), new pharmaceutical drugs cannot be marketed in the United States unless the sponsor of the drug demonstrates to the satisfaction of the FDA that the drug is safe and effective for each of its intended uses. 21 U.S.C. §§ 355(a), (d). A drug receives FDA approval only for treatment of specified conditions, referred to as "indications." 21 U.S.C. §§ 352, 355(d). For each indication sought a manufacturer must provide condition-specific safety and efficacy information. *Id.* The FDA also determines the particular dosage (or range of dosages) considered safe and effective for each indication.

33. To determine whether a drug is "safe and effective," the FDA relies on information provided by a drug's manufacturer; it does not conduct any substantial analysis or

studies itself. Applications for FDA approval (known as New Drug Applications or "NDAs") must include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether or not such drug is effective in use." 21 U.S.C. § 355 (b)(1)(A). FDA approval of prescription drugs is wholly dependent upon the accuracy of information provided by drug manufacturers. *See generally* Wayne A. Ray & Michael Stein, *Reform of Drug Regulation—Beyond an Independent Drug-Safety Board*, 354(2) NEJM 194 (Jan. 12, 2006).

34. FDA approval does not require that a new drug be more effective or safer than other drugs approved to treat the same condition. Neither does it require that the drug be cost-effective. A drug must only be shown to be more effective than a placebo in treating a particular condition, without any statistically significant safety findings. Comparative data showing performance as compared to existing drugs is not required; the FDA has no basis for determining that one drug is better than another drug.

35. Because short-term studies are accepted, drug applications often do not contain long-term data on the safety or efficacy of the drug. Approval of a new drug generally contains a requirement that the manufacturers pursue further long-term studies, but two-thirds of the promised studies never materialize and the FDA lacks any enforcement authority to require the manufacturer to complete these studies. Many of the effects of newly-approved drugs could not possibly be known at the time of FDA approval, particularly the long-term effects of taking a medication, given the short length of and relatively few participants in the clinical trials conducted for approval. *See AP Analysis: How a Drug's Risks Emerge*, N.Y. Times, May 23, 2007. There is no systematic provision requiring drug companies to conduct—or provide results from—post-marketing studies.

36. The FDA often finds itself in a quandary: "Safety and speed are the yin and yang of drug regulation. Patients want immediate access to breakthrough medicines but also want to believe the drugs are safe. These goals can be incompatible." Gardiner Harris, *Potentially Incompatible Goals at F.D.A.: Critics Say a Push to Approve Drugs Is Compromising Safety*, N.Y. Times, June 11, 2007, at A14.

37. The drug's label, included as a printed insert in the drug's packaging, must also be approved by the FDA as part of the original New Drug Application ("NDA"). The approved indications and respective dosage information appear on the package insert ("the label"). 21 U.S.C. §§ 352, 355(d). Labels are the primary means of providing prescribing physicians and their patients with important information on a drug's risks and benefits.

2. FDA Regulation After Approval.

38. After a drug is approved, the FDA continues to exercise control over the product labeling. To protect patients from safety concerns, the FDA may require a label change to reflect the increased risk of various side effects or interactions, restrict a drug's indications, or, in extreme cases, force a withdrawal from the market. *See* 21 C.F.R. § 201.57(3).

39. FDA regulations restrict how drug companies may market and promote approved drugs. *See* 21 U.S.C. §§ 331, 352; 21 C.F.R. § 314.81. Drug labels—"labels" include all marketing and promotional materials relating to the drug—may not describe intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352. Illegal "misbranding" can result in criminal penalties. *See* § 333.

40. The same general requirements about the promotion of prescription drugs apply to both professional and consumer-oriented marketing. In particular, promotional materials may only make claims that are supported by "substantial" scientific evidence (according to strict

scientific procedures) and they may not be false or misleading. FDA oversight helps ensure a "fair balance" in all promotional claims and materials. Federal regulations require that the risks as well as the benefits must be clearly identified and given appropriate prominence. Promotional materials must be consistent with the FDA-approved product labeling. This restriction pertains to the clinical indications for which the drug has been approved as well as the dosing regimen that is supported by the clinical trials that were undertaken to establish safety and efficacy.

41. Manufacturers like Defendants BMS and Par, wishing to market or otherwise promote an approved drug for uses other than those listed on the approved label, must resubmit the drug for a series of clinical trials similar to those required for the initial FDA approval. *See* Food and Drug Administration Modernization Act of 1997 ("FDMA"), 21 U.S.C. §§ 360aaa(b), (c); *see also* 21 C.F.R. § 314.54 (outlining the administrative procedure for filing an application for a new indication); 21 U.S.C. §§ 301 *et seq.* A supplemental NDA must be filed. Unless and until an additional indication is approved by the FDA, the unapproved use is considered to be "off-label."

42. Off-label information can only be distributed at the request of a health care provider. 21 U.S.C. §§ 360aaa-366.

3. DDMAC's Limited Ability to Regulate Drug Maker Marketing and Promotion.

43. The FDA's Division of Drug Marketing, Advertising and Communications ("DDMAC") is charged with overseeing the marketing and promotion of approved drugs to ensure that advertisements are not false or misleading, provide a fair balance between the benefits and risks of the drug, and do not include off-label uses. *See* Statement by Janet Woodcock, M.D. Before the Senate Special Committee on Aging.

44. DDMAC's effectiveness in regulating off-label promotion is limited. In 2003, the entire staff consisted of forty members, with twenty-five reviewers responsible for reviewing all drug advertisements and promotional materials. Moreover, drug materials do not have to be pre-approved. FDA review of promotional materials occurs, if it does at all, after the materials have already appeared in public. Woodcock Statement, *supra*. Upon finding a violation, DDMAC generally requests, but does not require, the company to stop using the promotional materials. *Id.* Sponsors occasionally are required to publicly correct product misimpressions created by false, misleading, or unbalanced materials. *Id.*

45. Once a drug has been approved, the FDA's statutory authority is limited to requesting label changes, negotiating restrictions on distribution with the manufacturer, and petitioning for the withdrawal of the drug from the marketplace. Title 21 of the Code of Federal Regulations requires that "as soon as there is reasonable evidence of a serious hazard with a drug," the "Warnings" section of the label should be revised to reflect this hazard.

46. FDA's ineffectiveness in policing off-label promotion was confirmed in a July 28, 2008 U.S. General Accountability Office Report, which found that the FDA took an average of seven (7) months to issue letters in response to off-label promotions. *See Drugs: FDA's Oversight of the Promotion of Drugs for Off-Label Uses* (GAO 08-835), http://www.gao.gov/new.items/d08835.pdf.

47. Among the Report's findings: (1) FDA does not have separate oversight activities to specifically capture off-label promotion; (2) FDA is unable to review all promotional submissions because of the volume of materials it receives and prioritizes its reviews in order to examine those with the greatest potential impact on human health; (3) FDA is hampered by the lack of a system that consistently tracks the receipt and review of submitted materials; (4) FDA

conducts limited monitoring and surveillance to identify violations that would not be identified through its review of submitted material—for instance, discussions between doctors and sales representatives; and (5) during calendar years 2003 through 2007, FDA issued 42 regulatory letters in response to off-label promotions requesting drug companies to stop dissemination of violative promotions.

4. Use of an Approved Drug Beyond Its Labeling Is Off-Label.

48. Any use of an approved drug for a purpose other than those indicated in the labeling is considered to be "off-label." *See* David C. Radley, *Off-Label Prescribing Among Office-Based Physicians*, 166 Archives of Internal Medicine 1021 (May 8, 2006). Physicians may prescribe drugs for off-label uses at their discretion. It is generally agreed that off-label prescribing can benefit both individual patients and patient populations as clinical experience leads to the formation of hypotheses to be tested in structured clinical trials. The FDA does regulate, however, off-label promotion by drug manufacturers.

49. Off-label uses of approved medications have not been subjected to the baseline FDA scrutiny that approved uses have been, and are thus riskier. The lack of an indication in the label should not be an issue, however, in the physician's managing of patients and prescribing a medication "off-label." Physicians and the community recognize that many drugs effective for a condition may not be labeled for that condition and may not have a strong body of evidence for or against their use.

50. When considering off-label prescribing, physicians depend on the patient-specific evidence they have available to them. This includes the particular patient, the severity of his problems, the successfulness of prior treatment, and the risks of not treating. Whether contemplating on- or off-label use, physicians also rely on personal experience,

recommendations from colleagues and academics, educational seminars, and clinical trials evidence. Much of what physicians rely on is information (or, as the case may be, misinformation) provided by sales representatives from drug makers, drug company sponsored CMEs and speaker programs, and drug company sponsored clinical trials.

V. THE DEFENDANTS' FRAUDULENT MARKETING SCHEME

51. At all relevant times, Defendants BMS and Par knew that Megace® and its follow-on Megace ES® were and are being paid or reimbursed by Government Programs, including Medicaid and Medicare Part D, as well as by the *Qui Tam* States.

52. Defendants BMS and Par knew, or it was reasonably foreseeable, that their promotion of Megace® and later Megace ES® would lead to the submission by physicians, pharmacists and Government-funded health plans of prescriptions ineligible for payment by Government Programs.

53. When Defendants BMS and Par decided to employ these illegal marketing practices, they knew or should have known that physicians, pharmacists, and federally-funded health programs would routinely and necessarily file claims with Government Programs for reimbursement for Megace® and Megace ES® prescriptions. But for Defendant BMS's and Par's illegal promotion, these off-label and misbranded prescriptions for Megace® and Megace ES® would not have been written. As a result, Defendants BMS and Par caused the submission of false claims to Government Programs for reimbursement of Megace® and Megace ES®. Defendants BMS and Par were the beneficiaries of these false claims for reimbursement of Megace® and Megace ES® prescriptions.

A. DEVELOPMENT AND MARKETING OF MEGACE® OFF-LABEL

54. In the early 1990s, Defendant BMS developed and patented Megace®, a liquid pharmaceutical composition of megestrol acetate indicated for the treatment of anorexia, cachexia, or an unexplained weight loss. Prior to this Megace® was also sold in tablet form in 20 mg and 40 mg strengths.

55. Megace® was approved by the FDA on September 10, 1993, for use in the management of anorexia, cachexia, and unexplained substantial weight loss in patients with HIV and AIDS. At the time, the FDA designated it an "orphan drug" for this use, referring to a pharmaceutical agent that has been developed specifically to treat a rare medical condition. Under the orphan drug law, companies that develop such a drug (a drug for a disorder affecting fewer than 200,000 people in the United States) may sell it without competition for seven years. Since the market for an orphan drug with such a limited application scope would, by definition, be small and thus largely unprofitable, the law was intended to motivate a manufacturer to address an otherwise unmet need for an orphan drug. The orphan drug designation for Megace® expired September 10, 2000.

56. Defendant Par filed an abbreviated new drug application ("ANDA") for megestrol acetate oral suspension with the FDA in 1999. Defendant BMS had obtained a formulation patent for Megace® Oral Suspension expiring in 2011. Par filed a paragraph IV certification as part of its ANDA submission regarding the formulation patent. BMS thereafter sued Par under the Hatch-Waxman Act, claiming patent infringement.

57. Before the District Court, Par moved for summary judgment of non-infringement. On December 14, 2000, the District Court entered an Order and Memorandum, granting Par's motion for summary judgment, and directing entry of judgment dismissing Bristol's complaint.

On December 26, 2000, Judgment was entered for Par. The Federal Circuit affirmed in July 2001.

1. Marketing Megace® Off Label

58. Antiretroviral drugs are medications for the treatment of infection by retroviruses, primarily HIV. When several such drugs, typically three or four, are taken in combination, the approach has come to be known as "highly active antiretroviral therapy," or "HAART." HAART drugs came into widespread use in the United States in or around 1996 for the treatment of HIV/AIDS. The use of HAART drugs radically changed the course of treatment for HIV/AIDS patients, enabling them to control the disease.

59. Until the late 1990's, Defendant BMS had marketed Megace® for its on-label use to treat anorexia, cachexia, and unexplained substantial weight loss in patients with HIV and AIDS. However, with the advent of HAART treatments for HIV/AIDS, Defendant BMS found that bottom of the on-label market for Megace® had dropped out.

60. As such, beginning at least as early as 1997, Defendant BMS developed a marketing plan to replace the shrinking on-label market for Megace® with off-label prescriptions for geriatric patients suffering from unintended weight loss and for palliative care for oncology patients.

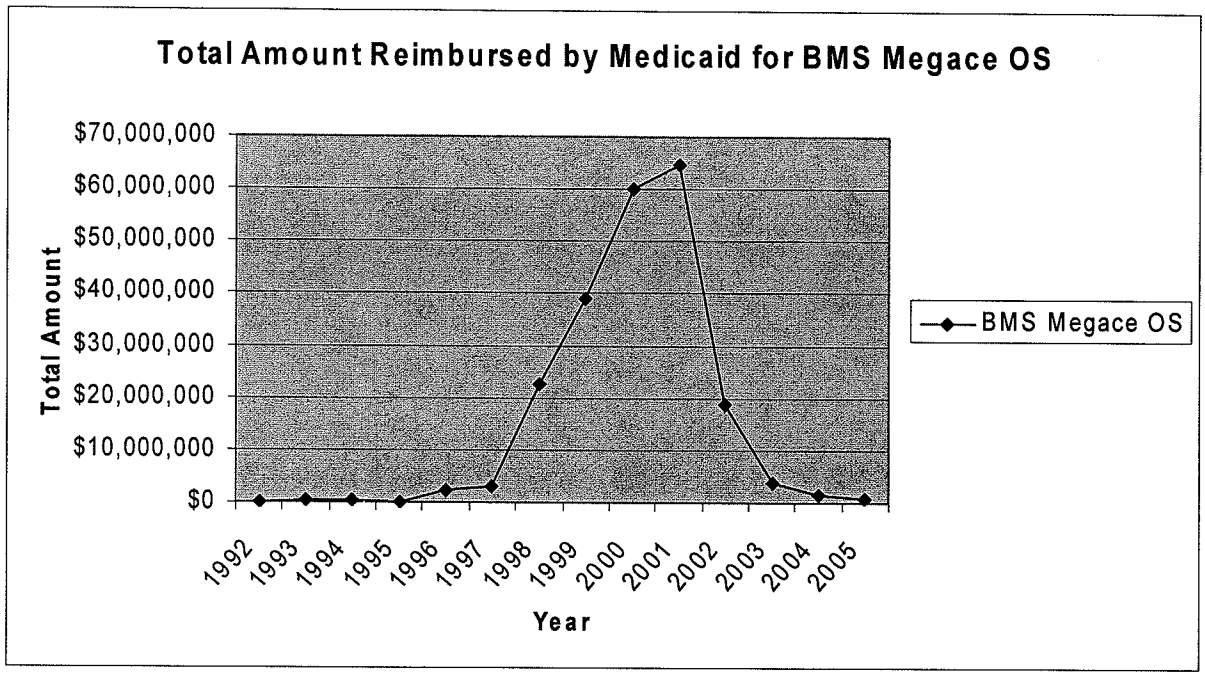
61. The Defendant BMS's employees who developed the Fraudulent Marketing Scheme for Megace® were David Chen, Megace® Director of Marketing, and Cheryl Mokrzecky, Associated Director of Marketing. At numerous quarterly sales meetings beginning at least as early as 1997, Defendant BMS immunology sales representatives were instructed by Defendant BMS to sell Megace® off-label for use in long-term care facilities and to treat oncology patients.

62. In addition to the Defendant BMS immunology sales force, Relator Elliott was directed to train Defendant Apothecon's sales force to promote Megace® off-label to lower decile physicians who treated few (or no) HIV/AIDS patients, and instead were only likely to be using Megace® off-label.

63. The Defendant BMS and Apothecon sales representatives had included in their marketing budgets amounts for lunches at nursing homes to promote Megace® off label.

64. In order to conceal the fraud, no long-term care physicians or their staffs were included on the immunology sales representative's call lists. However, the sales representatives were expected to call on long-term care physicians and their staffs, and were given sales bonuses related to increasing the off-label sales to patients in nursing homes.

65. By 2000, Defendant BMS's Fraudulent Marketing Scheme had converted Megace® into a drug whose sales in 2000 were $180 million, an increase of 58% over the previous year. With on-label sales plummeting, the 58% increase was all due to Defendant BMS's off-label promotion of Megace®. Here is a table showing the rapid increase in Medicaid payments for Megace® due to Defendant BMS's Fraudulent Marketing Scheme, and showing the decline in payments once the generic megestrol acetate came on the market in 2001:



The increase in Medicaid payments from 1997 to 1998 illustrates the growth of the BMS Fraudulent Marketing Scheme. In 1997, there were only $2,882,460.32 in Megace® Medicaid payments. In 1998, there was an incredible jump in Medicaid payments to $22,668,405.47, a 786% increase over the prior year, all of it related to Defendant BMS's off-label promotion. At the point in time when the on-label use of Megace® was declining, Defendant BMS was able to grow Megace®, largely due to the off-label business, in 1999 to $39,094,397.58 (a 72% increase), and in 2000 to $59,897,955.56 (a 53% increase).

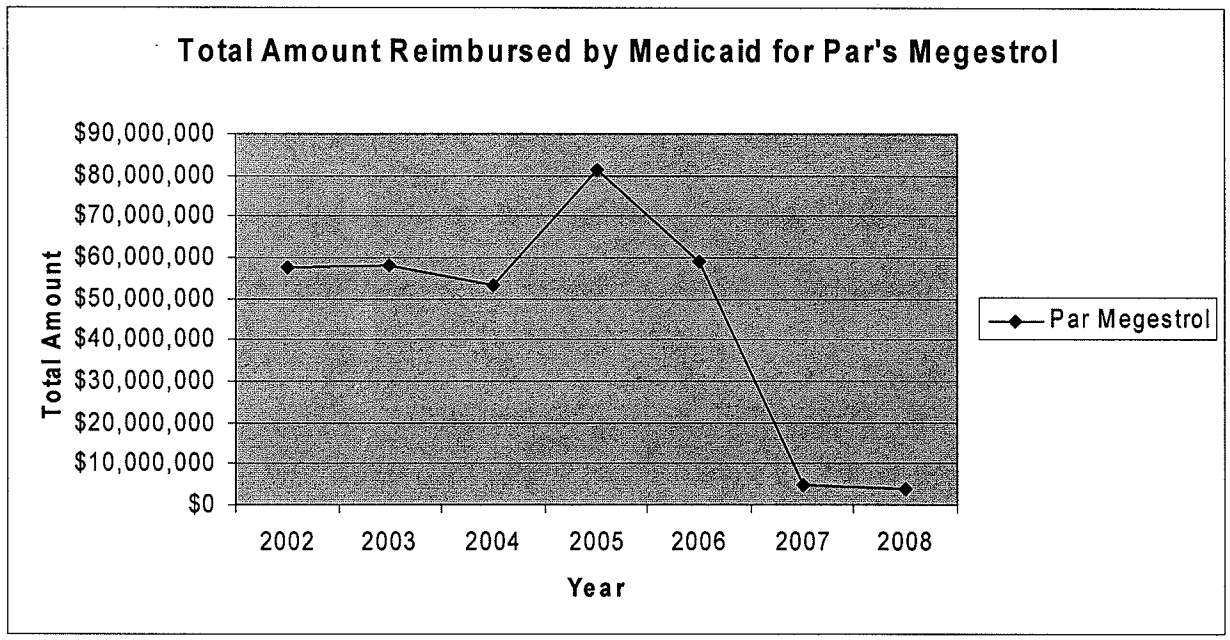
2. Defendants Conspire to Sell Megace® Off-Label

66. On July 25, 2001, the FDA granted marketing approval for Defendant Par's generic megestrol acetate, and Defendant Par then began selling the generic shortly thereafter.

67. On September 2, 2003, Defendants announced they had entered into an agreement under which Par would license the Megace® trade name to be used in a potential new product being developed by Par. Under the terms of the agreement, Defendant Par also provided funding

to support active promotion of Megace® brand during the remainder of 2003 and throughout 2004 to "help retain brand equity and awareness among physicians."

68. As such, Defendants jointly agreed that Defendant BMS would continue its off-label promotion of Megace® through 2004. Here is a chart showing the sales of Defendant Par's generic megestrol acetate, including Medicaid sales for Defendant Par's product marketed as Megace® through the BMS sales force in 2003 and 2004, again largely off-label sales to long-term care and oncology patients:



69. Between 1997 and 2005 there were 1,302,942 Megace® prescriptions reimbursed by Medicaid programs, or 402,335,166 units, for a total of $213,839,481, the majority of it for off-label prescriptions.

B. DEVELOPMENT AND OFF LABEL PROMOTION OF MEGACE ES®

70. The FDA approved Defendant Par's Megace® ES (625mg/5mL) on July 5, 2005 for the treatment of anorexia, cachexia or an unexplained, significant weight loss in patients with AIDS, and Defendant Par began marketing Megace ES® shortly thereafter.

71. Defendant Par has at all material times hereto touted Megace ES® as an advanced, concentrated formulation of its generic megestrol acetate (marketed as Megace®) with improved bioavailability in people who have not eaten (fasted condition), more rapid onset of action, more convenient dosing and a lower dosing regimen compared with the original marketed formulation of megestrol acetate oral suspension. Patients are administered a teaspoon (5mL) of the new Megace ES® formulation once daily, compared with a daily 20mL dosage cup of the original megestrol acetate formulation.

72. Defendant Par's sales of Megace ES® were substantial, totaling $209,086,000 through the end of 2008. During this same time period, there were 1,071,391 prescriptions written for Medicaid alone, totaling $56,010,614 paid for Megace ES®, almost all of it for off-label prescriptions. On information and belief, the Medicare Part D reimbursements during this time for Megace ES® would have been at least as much as the Medicaid amounts.

73. The Megace ES® formulation represented a line-extension of Defendant Par's generic megestrol acetate oral suspension. Although Par was the only generic manufacturer selling megestrol acetate in 2001, by 2005 there were three other generic drug makers selling the generic version (Morton Grove, Roxane, and Teva). Thus, by the launch of Megace ES® in 2005, Defendant Par faced stiff competition from not only its own generic, but also from other much cheaper megestrol acetate products. As such, Defendant Par undertook an intense off-label promotion scheme to grow the off-label use of Megace ES®.

74. From the outset of the launch in July 2005, the market for the on-label use of Megace ES® was limited because there are relatively few patients suffering from unexplained weight loss due to HIV/AIDS. Even though the HIV/AIDS epidemic has claimed the lives of over 550,000 Americans, today about 1.1 million Americans are living with HIV, the virus that

causes AIDS. While there are still many patients living with HIV, over the last ten (10) years increasingly these patients' HIV is being controlled with the use of the "cocktail" drugs used to treat the condition. As such, Par found itself with a shrinking on-label market for Megace ES®.

75. At the time of the Megace ES® launch, sales representatives (including Relator Lundstrom) were told that the company was applying for additional uses of Megace ES® for the treatment of weight loss due to cancer and for use with geriatric patients. In April 2006, Par announced it had initiated the first of two phase III trials of megestrol acetate concentrated suspension in cancer-induced anorexia. Only five months later, the company announced that it was abandoning the phase III trials due to inadequate enrollment.

76. As for Par's efforts to gain the geriatric indication, this too was abandoned due to health concerns related to deep vein thrombosis risk ("DVT"). Specifically, several "negative" studies reported the risk of DVT:

- A study of nineteen residents prescribed megestrol acetate between November 1997 and July 1998 found a "high incidence of deep vein thrombosis was identified among nursing home residents treated with megestrol acetate, even among ambulatory individuals with no other known risk factors." Bolen, et al., Journal of the American Medical Directors Association, November/December 2000.
- A retrospective chart review of the 816-resident Bronx division of the Jewish Home, a large teaching nursing home in New York City, found the incidence of DVT noted in this study was six-fold larger than one would expect in the absence of other factors. Kropsky, et al., "Incidence of Deep-Venous Thrombosis in

Nursing Home Residents Using Megestrol Acetate," Journal of the American Medical Directors Association, September/ October 2003.

- A scientific literature review found that "caution is warranted in using megestrol acetate off-label in geriatric nursing facility residents, particularly female residents and residents with impaired mobility." Marshall, "Megestrol Acetate Therapy in Geriatric Patients: Case Reviews and Associated Deep Vein Thrombosis," The Consultant Pharmacist. September 2003, Vol. 18, No. 9.

77. In the region of the country where Relator Lundstrom was asked to promote Megace ES®, there were relatively few HIV/AIDS patients who needed on-label treatment using the drug. At the time, by far the largest markets for Megace ES® were in converting off-label use of the generic megestrol acetate, which generated some 90% of the use to treat weight loss in oncology patients and in geriatric patients in nursing homes.

1. Use in Nursing Homes

78. Shortly after the time of the launch of Megace ES® in July 2005, John Ameres, Director, Branded Marketing for Defendant Par on September 7, 2005, sent an email to the entire senior sales and marketing management at Par, regarding "appropriate promotion of Megace ES in nursing homes." At the time, Ameres announced that "[w]e are looking closely at the long-term market to determine the best manner to educate those nursing homes that treat AIDS patients as to the difference between megestrol acetate and such Megace ES®. It is clear that the treatment of AIDS is relevant to many nursing homes and such facilities will likely be added to our promotional efforts in the future." This was not true. Very few AIDS patients were actually being treated any longer in nursing homes. The real market in nursing homes was the off-label use to treat geriatric patients for unintended weight loss unrelated to HIV/AIDS.

79. At the time of the launch, Relator Lundstrom and the other Megace ES® sales representatives received "call files" which provided representatives with the doctors they are to call on. On sales representatives' call files for potential sales of Megace ES® were all the physicians who had been megestrol acetate prescribers, including numerous physicians who would have had no occasion to treat patients for the on-label conditions for which Megace ES® was approved (family medicine, gerontologists, cardiovascular disease specialists, oncologists), but on whom sales representatives were expected to market Megace ES® nonetheless.

80. Relator Lundstrom's call file, for example, included over 140 physicians, of whom some 125 were family medicine, 12 were oncologists, and only 2 or 3 were physicians who specialized in the treatment of HIV/AIDS. Because of the treatment of HIV/AIDS is highly centralized in specialist physicians, only these two or three specialists on Relator Lundstrom's call file were actually treating patients who might be prescribing Megace ES® on-label.

81. The call lists prepared by the company were thus directly contrary to Par's own compliance policy. The PAR Pharmaceutical Health Care Compliance Guide specifically states on page 8 that "[i]t is inappropriate to market a PAR product to [health care professional] audiences who appear to have little or no opportunity to use that product consistent with the approved product label." This policy was not only ignored, it was flagrantly ignored.

82. By late 2005 and early 2006, it had become clear to Par's sales management that the only way to grow the limited market share of Megace ES® was to actively market the drug "where the business was" – *i.e.,* in nursing homes to medical directors, directors of nursing ("DONs"), assistant directors of nursing ("ADONs"), and dieticians. As such, the Par sales representatives' call panels were "realigned" at this time to focus even more on growing the off-label sales in nursing homes.

83. Relator Lundstrom and the other Par sales representatives were therefore required to call on physicians and their staffs who treated a high percentage of nursing home patients to "convert" their use from generic megestrol acetate to Megace ES®. As part of the efforts to grow the off-label use of Megace ES®, Relator Lundstrom thus was directed to conduct regular in-services for nursing home personnel, including medical directors, DONs, ADONs, dieticians, and other staff. The message he was to deliver was that Megace ES® was a better choice for their residents suffering unexpected weight loss without regard to whether this was consistent with the product label or Par's compliance policy.

84. During the promotion of Megace ES® in nursing homes, Par sales representatives were to emphasize the message of its superiority over the old megestrol acetate. In the detail, however, Par representatives were not to mention three negative studies, showing that Megace ES® had a much greater risk to geriatric patients related to DVT, a potentially life-threatening condition, or risk related to renal insufficiency.

85. At all times material hereto, nursing home patients were particularly appealing targets for Defendant Par's fraud scheme because many of these patients are "dual eligible" -- patients who have both Medicare Part D drug coverage and are also eligible for Medicaid drug benefits. Defendant Par's sales representatives were specifically directed to target these patients because (a) they would have no co-payment limits impacting the choice of the more expensive Megace ES® ($500 per month) as opposed to the generic megestrol acetate (which could cost as little as $4 per month in the local Walmart pharmacy), and (b) state Medicaid formularies would "have little impact on Megace ES utilization."

86. Nursing homes became such a lucrative part of the marketing of Megace ES® that beginning in 2006 Defendant Par created a specific sales position, Regional Account Managers

("RAMs"), whose job it was to call in the nursing home sector of the market. Because there never was a specific RAM in his region of the country, Relator Lundstrom assumed these RAM responsibilities.

2. Promoting Megace ES® Off-Label to Dr. David P. Kraft for Medicare Part D and Medicaid Nursing Home Patients

87. Dr. David P. Kraft, 6565 S. Yale Ave, Suite 80, Tulsa, Oklahoma, at all times material hereto served as the medical director for multiple nursing homes and/or admitted patients to multiple nursing homes, including Forest Hills, 4304 W. Houston Street, Broken Arrow, OK 74012-4519; Maple Wood, 6202 East 61st Tulsa, OK 74136; Ambassador Manor, 1340 E. 61st Street Tulsa, Oklahoma 74136; Tulsa Nursing Center, 10912 E. 14th Street, Tulsa, Oklahoma 74128; and Grace Living Center, 711 North 5th Street, Jenks, Oklahoma 74037.

88. Relator Lundstrom had Dr. Kraft on his call file from the outset. Of the hundreds of patients in the nursing homes where Dr. Kraft was medical director and/or admitting patients, perhaps only 1 or 2 patients were HIV/AIDS patients. As such, there was little (or no) reason for Relator Lundstrom to be detailing Megace ES® to Dr. Kraft or to his staff.

89. Since Dr. Kraft was responsible for so many patients, Relator Lundstrom rarely ever actually detailed Dr. Kraft directly. Instead, he regularly detailed Dr. Kraft's long-term care staff where he conducted frequent in-services, which included free meals to the staff. Dr. Kraft's staff would then fill out the Megace ES® prescriptions, and Dr. Kraft would sign them at the end of the day, generally without looking at what he was signing. At all times material hereto, a large portion of the patients Dr. Kraft "treated" were Medicare Part D and/or Medicaid patients, many of whom were converted to the off-label use of Megace ES® following Relator Lundstrom's details.

90. Relator Lundstrom detailed Megace ES® to Dr. Kraft's staff on multiple occasions, starting in 2005. For example, between September 2007 and August 2008, Relator Lundstrom detailed Dr. Kraft's staff some 25 occasions. During this time, Dr. Kraft prescribed Megace ES® 244 times for his elderly nursing home patients. Of this, he wrote 101 Megace ES® first-time prescriptions for these elderly patients. Nearly all of these prescriptions for Megace ES® were written off-label, mostly for Medicare Part D and Medicaid patients.

3. Promoting Megace ES® Off-Label at Glenpool Health Care Center

91. Relator Lundstrom targeted off-label promotion of Megace ES® on call panel physicians Dr. Roger Kinney and Dr. Rodger Spillars (and their staffs), who regularly admitted patients to Glenpool Health Center, 1700 E 141st St, Glenpool, Oklahoma 74033.

92. On April 21, 2008, he met with the Assistant Director of Nursing (ADON), who agreed to go through patient charts to identify Megace ES® candidates – *i.e.,* those patients who were currently taking megestrol acetate oral suspension for longer than three months with no weight gain increase. There were no AIDS patients at this facility.

93. On June 6, 2008, the ADON informed Relator Lundstrom that all the candidates had been identified and switched to Megace ES®. On June 8, 2008, the ADON confirmed off-label switches to Megace ES® were all Medicare Part D and dual eligible patients, and that there were no reimbursement issues.

94. On August 12, 2008, Relator Lundstrom met with Wanda Bell, the new Director of Nursing (DON) at Glenpool, who confirmed all but two megestrol acetate oral suspension patients were taking Megace ES®. Most were patients of Dr. Kinney's and Dr. Spillars'.

95. On October 30, 2008, Relator Lundstrom met with the DON and ADON, who reported six patients were currently on megestrol acetate oral suspension ("MAOS"), but that they would monitor and switch to Megace ES®, if necessary.

96. Relator Lundstrom also on October 30, 2008 met with Pam Shelton, consultant pharmacist with the long term care pharmacy provider Sequoia Pharmacy Services, a division of Omnicare, who said she had had a problem with the proper reimbursement code for Megace ES® with one insurer when the diagnosis of "appetite stimulation" was used on the prescription order for Megace ES®. Ms. Shelton changed the diagnosis to "senile cachexia" and the request was approved.

4. Promoting Megace ES® Off-Label at Rolling Hills Care Center

97. Relator Lundstrom regularly off-label detailed the long-term care staff at Rolling Hills Care Center, 801 North 193rd East Avenue, Catoosa, Oklahoma 74015. The Rolling Hills Medical Director was Dr. Art Coder and the ADON was Karen Sappington.

98. On May 7, 2008, Relator Lundstrom provided lunch to Ms. Sappington, and discussed differences between MAOS and Megace ES®. She agreed to look through patient charts to identify Megace ES® candidates. There were no AIDS patients at this facility and all candidates Ms. Sappington identified were long-term care patients.

99. On May 23, 2008, he met again with Ms. Sappington who indicated she had converted six long term care patients to Megace ES® and there were no reimbursement issues.

100. On August 12, 2008, Relator Lundstrom met again with Ms. Sappington, who stated she had attempted the conversion of ten long-term care patients and was informed by Rick Jones, Pharm D of the long term care pharmacy provider Pharmcare, that Megace ES® was "not covered" on four of the ten patients. Relator Lundstrom then obtained plan names and

investigated by calling Pharmcare directly where he learned that the plans required either a formulary exception or prior authorization. Relator Lundstrom thereafter went to the plan websites, downloaded appropriate forms, which he provided to Ms. Sappington, who then completed the forms. When Dr. Coder signed the forms, three of the four patients' claims were then approved. All three were long-term care Medicare Part D and dual eligible patients.

5. Promoting Megace ES® Off-Label at Maplewood Care Center

101. Relator Lundstrom regularly off-label detailed Megace ES® to the staff at Maplewood Care Center, 6202 Eat 61st St, Tulsa, Oklahoma 74136. Drs. Spillars, Harris, Kraft, Aggarwal and Gearhart all admitted patients to Maplewood. He regularly met with the MDS coordinator to promote the off-label use of Megace ES® for use in the elderly. After numerous discussions during the prior twelve months and sporadic use of Megace ES® by the facility, she ultimately agreed to identify and recommend MAOS conversions to Megace ES® for all patients who were still on MAOS therapy after 3 months with no increase in weight. She thereafter identified ten long-term care patients on MAOS and recommended conversion of two to Megace ES®.

102. On March 13, 2009, Relator Lundstrom conducted a lunch in-service for the Maplewood staff. During this in-service, the MDS agreed to recommend additional patients for Megace ES® from her list.

103. Most of the Maplewood patients who were converted to the off-label use of Megace ES® were Medicare Part D patients and/or dual eligible patients. There were no HIV/AIDS patients on the list.

6. Promoting Megace ES® Off-Label at Broken Arrow Nursing Home

104. Relator Lundstrom likewise regularly off-label detailed the long-term care staff at Broken Arrow Nursing Home, 424 NorthDate, Broken Arrow, Oklahoma 74012. Dr. Art Coder and Dr. Douglas Holte regularly admitted patients to this facility.

105. On December 19, 2008, Relator Lundstrom met with Barbara Young, DON, and discussed unintended weight loss incidence and converting MAOS patients to Megace ES®. Ms. Young agreed to identify candidates for Megace ES® and recommend to Drs. Coder and Holte.

106. On February 9, 2009, Ms. Young informed Relator Lundstrom that she had switched one patient to Megace ES®, but the insurance company had denied the claim, requiring failure of MAOS before trying Megace ES®. Relator Lundstrom then discussed the prior authorization process with Ms. Young and discussed the dual eligible plans in Oklahoma. He also provided her with the necessary prior authorization forms to complete for these patients.

107. On March 25, 2009, Relator Lundstrom conducted an in-service with four Broken Arrow nurses where he discussed benefits of Megace ES® compared to MAOS. All four nurses agreed to identify MAOS patients who were not responding and recommend conversion to Megace ES®. There were no AIDS patients at this facility. All of these patients were Medicare Part D and/or dual eligible.

7. Promoting Megace ES® Off-Label at Forest Hills Health Care Center

108. Relator Lundstrom regularly off-label detailed Megace ES® to the staff at Forest Hills Health Care Center, 4300 West Houston, Broken Arrow, Oklahoma 74012. Drs. Kraft and Adkisson admitted a number of patients to this facility.

109. Between August 6, 2008 and April 6, 2009, Relator Lundstrom conducted several in-services for Forest Hills staff. The facility went through a control change and numerous staff

changes during this time. During this time, Relator Lundstrom worked with Dr. Kraft's nurse, Jackie Fullerton, and the dietician at Forest Hills, in identifying Megace ES® candidates.

110. On February 10, 2009, the dietician indicated that two long-term care patients had been started on Megace ES® while six to eight patients remained on MAOS. She agreed to watch and convert to Megace ES® if no response to MAOS after three months.

111. On April 6, 2009, Relator Lundstrom again called on Forest Hills, and the dietician indicated that there were two patients on Megace ES® and two on MAOS. She also said there are no Medicaid beds at this facility, and that their patients were primarily Medicare Part D.

112. Throughout this time, Relator Lundstrom worked extensively with Dr. Kraft's nurse, Jackie Fullerton, since Dr. Kraft was affiliated with approximately six local long-term care facilities and had a high long-term care patient population. In addition, he did so because Dr. Kraft was identified as a high target according to the call file provided by Defendant Par. Relator Lundstrom met with Ms. Fullerton approximately twenty-five times over a twelve month period regarding conversion of MAOS to Megace ES® at Dr. Kraft's long-term care facilities.

8. Promoting Megace ES® Off-Label at Grace Living Centers

113. Relator Lundstrom regularly off-label promoted Megace ES® at Grace Living Centers, 4717 West Okmulgee, Muskogee, OK 74401. Drs. Anderson and Lambert admitted numerous Medicare Part D patients at this facility.

114. Between February 2, 2008 and March 3, 2009, Relator Lundstrom met with the DON, Audrey Smith, the ADON, and Bonnie Sides, LPN. He had numerous discussions regarding Megace ES® with these individuals between the dates of February 7, 2008 and March

3, 2009. However, due to high staff turnover, Megace ES® use was sporadic as newly appointed staff required education about Megace ES® and reimbursement was a continuing problem.

115. On June 18, 2008, he met with Ms. Sides, who stated that six of seven of the MAOS patients had been switched to Megace ES®.

116. In approximately August 2008, Ms. Sides informed Relator Lundstrom that coverage of Megace ES® was challenging. Relator Lundstrom then requested a list of insurers who were raising coverage issues. Ms. Sides in turn requested the plan names from Pharmacy Solutions, the long term care pharmacy provider for Grace Living Centers; however, this information was never received.

117. On October 15, 2008, Relator Lundstrom called on Grace Living Centers and was informed by the ADON that all its patients had been switched back to generic MAOS. He then discussed the prior authorization process, provided reimbursement forms for Oklahoma benchmark plans, and then explained that the term "senile cachexia" was the verbiage necessary to convert coverage from MAOS to Megace ES® for long term-care use. On October 23, 2008, Ms. Sides resubmitted the claims with the diagnosis of "senile cachexia" and coverage of Megace ES® was approved by the plans. None of these patients was HIV/AIDS, and all were Medicare Part D and/or dual eligible.

9. Marketing Megace ES® Off-Label at Nursing Home Trade Shows

118. The PAR Compliance Guide specifically states on page 8 that "all promotional activity, including ... display booths and exhibits shall be directed only to those [health care professionals] who would have reason to use the PAR product being promoted consistent with the approved product labeling." This policy, too, was flagrantly violated.

119. At all times material hereto, sales representatives were expected as part of their sales to market Megace ES® at trade shows, including specifically nursing home trade shows. One such trade show where Relator Lundstrom exhibited Megace ES® was the Oklahoma Association of Health Care Providers, at which some three hundred long-term care professionals were in attendance.

120. The sole focus of the Par exhibit was Megace ES®, with numerous product give-aways being provided to attendees, including magnifying rulers, magnets, ball point pens, and hand sanitizer sprayers, all adorned with "Megace ES®." In addition, attendees were given the Megace ES® LTC "Sell Sheets" and "Sell Sheet Fact Sheets" as take-aways from the exhibit.

121. Few, if any, of the attendees at the Oklahoma long-term care trade show would have occasion to "use [Megace ES] . . . consistent with the approved product labeling."

10. Misleading Medical Information Letters Failing to Mention DVT Risk

122. Pursuant to page 9 of the PAR Compliance Guide, it was permissible to provide a health care professional off-label information about a PAR product that was "unsolicited" inquiries, "provided that it is part of an exchange of sound scientific information and does not contain any corporate claims of safety or effectiveness for the off-label use." The PAR Medical Affairs Department was to handle all such responses, which was to respond in a "medically accurate and balanced manner."

123. On information and belief, the responses concerning off-label use of Megace ES® for geriatric patients were in many instances not only inaccurate, they were materially inaccurate. For example, in a response entitled "Use in Geriatric Patients," there is absolutely no mention of the fact that use of Megace ES® in geriatric patients carried a much greater risk of DVT, and

instead included references to anecdotal studies showing weight gain in the elderly with no mention whatsoever about the severe DVT risk.

124. The DVT risk was material information that Par should have mentioned in the medical information letter. Indeed, this risk was so great that Par on May 30, 2008 submitted a supplemental new drug application to add the DVT risk to the product labeling.

11. Use to Treat Cancer Patients

125. One of the announced goals at the launch of Megace ES® was that the company was seeking an oncology indication.

126. In April 2006, Par announced that it had initiated the first of two phase III trials of megestrol acetate concentrated suspension in cancer-induced anorexia.

127. On September 5, 2006, Par announced that, due to "slow patient enrollment," it had decided to discontinue a phase III clinical trial of Megace ES® in cancer-induced anorexia, and stated it "intends to discuss alternate clinical development options with the FDA."

128. Despite the fact that Par had failed to obtain the oncology indication for Megace ES®, its sales representatives were nonetheless expected to call on oncologists to convert them from using megestrol acetate. Relator Lundstrom and the other Par sales representatives all had numerous oncologists on their call files. For example, on Relator Lundstrom's initial call file, he had numerous oncologists.

12. Defendant Par Paid Multiple Speakers To Unlawfully Promote Megace ES®.

129. The PAR Compliance Guide at page 12 states "[i]t is illegal and against PAR policy to select advisors and consultants to . . . promote . . . off-label uses of a product . . . ."

130. Defendant Par paid influential speakers to promote Megace ES®, including speakers who Defendant Par knew only had expertise in off-label uses and who would thus only make off-label presentations.

131. One such example was a presentation given by Frank Breve, Ph.D., from Pharma Tech Consulting Group, LLC, in Blackwood, New Jersey. Dr. Breve spoke to a group of long-term care health care professionals on April 1, 2009 on the use of Megace ES® in the long-term care setting for which he received an honoraria of $750.00. The entire presentation was off-label.

13. Using Quota And Credit Programs To Induce Sales To Doctors And Facilities Who Do Not Use Megace ES® On-Label.

132. Defendant Par's national sales strategy included an Incentive Compensation Program for Megace ES® that incentivized the sales force to sell to doctors who could not treat their patients using Megace ES® on-label. Defendant Par knew that these programs created a working environment that was conducive to promoting Megace ES® for as many uses and as wide a patient base as possible. The quota and credit programs were instituted immediately upon Megace ES®'s launch in 2005.

133. Defendant Par's quota system required Megace ES® sales representatives to detail any physician on their call list (regardless of specialty) and awarded them with bonuses based on sales of Megace ES®. Megace ES® sales representatives that exceeded quota would be paid additional bonus dollars and additional chances of winning award trips. The prescribers Par included in its quota and credit programs were doctors that would not normally treat patients with Megace ES®'s approved indications.

VI. DEFENDANTS' FRAUDULENT MARKETING SCHEME VIOLATED FEDERAL PROGRAM LIMITATIONS.

134. Defendants could lawfully market Megace® and Megace ES® in a number of ways, including the dissemination of truthful information that complies with federal law. Once a drug is approved by the FDA for a certain use (or "indication"), it must be promoted by the manufacturer for that use, and that use only. After FDA approval, Defendants could only promote Megace® and Megace ES® to treat the then FDA-approved HIV/AIDS conditions. However, at no time could Defendants lawfully promote Megace® or Megace ES® for any other non-FDA approved purpose.

135. In violation of federal law, Defendants knowingly and deliberately promoted Megace® and Megace ES® for non-FDA approved uses ("off-label" uses) that Defendants knowingly, or could reasonably foresee, would lead to violations of federal Medicaid statutes and regulations designed to restrict reimbursement to Government Programs such as Medicaid.

136. Government Programs, including the Medicaid program, also rely on the FDA's findings regarding what uses for approved drugs are safe and effective. Whether a drug that is FDA-approved for a particular use will largely determine whether a prescription for that drug will be reimbursable under Government Programs, including the Medicaid program.

137. In 1990, Congress passed the Budget Reconciliation Act which limited reimbursement for prescription drugs to "covered outpatient drugs." Covered outpatient drugs only include drugs used for "medically accepted indications." A medically-accepted indication is a use which has been approved by the FDA or one which is supported by specific drug reporting compendia set forth in the Medicaid statute, 42 U.S.C. § 1396r-8(k)(6). Reimbursement by Medicaid is, with only one rare exception, prohibited if the drug is not being used for a medically accepted indication. 42 U.S.C. § 1396r-8(k)(3).

138. Congress has adopted a compendia-based system for determining appropriate Medicaid and Medicare Part D reimbursements for off-label uses of a "covered outpatient drug." Soc. Sec. Act § 1927(g)(1)(B)(i) and (k)(6) (permitting reimbursements for drug uses that "(i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results"). Thus, the only way a prescription could be allowed under the Medicaid and Medicare Part D statutes was if the particular off-label Megace ES® indication had been approved in one of the compendia identified in § 1927(g)(1)(B)(i) to be eligible for reimbursement under Medicaid, and other federal reimbursement programs.

139. The most commonly-available of these compendia, DRUGDEX, does not support the off-label uses for Megace® and Megace ES® promoted by Defendants. As such, Medicaid and Medicare Part D reimbursements for Megace® and later for Megace ES® prescriptions related to oncology or geriatric patients were not eligible for reimbursement and should not have been made.

140. Similarly, off-label indications qualify as "medically accepted indications" for Medicare reimbursement if they appear on the identified drug reporting compendia. Reimbursement under Medicare is only available to a physician if the services he or she provided were "medically required," and he or she certifies that the services performed were medically necessary. 42 U.S.C. § 1395n(a)(2).

141. Defendants promoted off-label indications of Megace® and Megace ES®, knowing they were not eligible for reimbursement because the indication was neither listed on the drug reporting compendia or the relevant fiscal intermediary's Local Coverage Determination ("LCD"), nor was it included on the FDA-approved product labeling. Furthermore, Defendants illegally promoted off-label uses without meeting the FDA

requirements, and without resubmitting Megace® and Megace ES® to the FDA testing and approval process as required by 21 U.S.C. § 360aaa *et seq.* Thus, claims for reimbursement of off-label Megace® and Megace ES® prescriptions fail to meet the eligibility requirements of Government Programs and the *Qui Tam* States. Defendants' off-label promotion of Megace® and Megace ES® resulted in reimbursement by Government Programs and the *Qui Tam* States for numerous false claims.

COUNT I
VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, (a)(1)

142. Relators incorporate herein by reference the preceding paragraphs of the Firsrt Amended Complaint as though fully set forth herein.

143. Defendants, knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, presented or caused to be presented, and may still be presenting or causing to be presented, to CMS, or other Government Programs, false or fraudulent claims for payment, in violation of, inter alia, 31 U.S.C. § 3729(a)(1).

144. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Megace ES® prescribed to patients enrolled in Government Programs.

145. As a result of Defendants' actions as set forth above in this complaint, the United States of America has been, and may continue to be, severely damaged.

COUNT II
VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3729, (a)(2)

146. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

147. Defendants' knowingly made and caused to be made and used materially false statements and records to get false and fraudulent claims paid by the United States in violation of, inter alia, 31 U.S.C. § 3729 (a)(2).

148. The United States of America, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid and may still be paying or reimbursing for Megace ES® prescribed to patients enrolled in Government Programs.

149. As a result of Defendants' actions as set forth above, the United States of America has been, and may continue to be, severely damaged.

COUNT III
VIOLATION OF FALSE CLAIMS ACT 31 U.S.C. § 3729(a)(3)
AS AGAINST ALL DEFENDANTS

150. Relators hereby incorporate by reference all allegations set forth in this First Amended Complaint, as though fully set forth herein.

151. Between at least September 2, 2003 and through 2004, defendants knowingly combined and conspired to defraud the Government by getting false and fraudulent claims paid or allowed by the Government for payment.

152. Each Defendant has acted with the intent to defraud.

153. The Defendants have committed acts in furtherance of the object of this conspiracy as set forth above.

154. As a proximate result of the aforesaid fraudulent conduct, the United States of America sustained damages in an amount to be proven at trial.

COUNT IV
VIOLATION OF THE STATE OF CALIFORNIA
FALSE CLAIMS ACT, CAL GOV'T CODE § 12650, *et seq.*

155. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

156. This is a civil action brought by Relators on behalf of the State of California against Defendants under the California False Claims Act, CAL. CODE § 12652(c).

157. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of California or its political subdivisions false or fraudulent claims for payment, in violation of CAL. CODE § 12651(a)(1).

158. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of CAL. CODE § 12651(a)(2).

159. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of CAL. CODE § 12651(a)(3).

160. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made

or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of California or its political subdivisions in violation of CAL. CODE § 1265 1 (a)(7).

161. The State of California, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

162. As a result of Defendants' actions as set forth above, the State of California, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT V
VIOLATION OF THE STATE OF COLORADO MEDICAID FALSE CLAIMS ACT, COLO. REV. STAT. § 25.5-4-304

163. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

164. This is a civil action brought by Relators on behalf of the State of Colorado against Defendants under the State of Colorado False Claims Act, COLO. REV. STAT. § 25.5-4-304.

165. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of COLO. REV. STAT. § 25.5-4-305(a).

166. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of COLO. REV. STAT. § 25.5-4-305(b).

167. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Colorado or one of its political subdivisions, in violation of COLO. REV. STAT. § 25.5-4-305(f).

168. The State of Colorado, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

169. As a result of Defendants' actions, as set forth above, the State of Colorado or its political subdivisions have been, and may continue to be, severely damaged.

COUNT VI
VIOLATION OF THE STATE OF CONNECTICUT FALSE CLAIMS ACT, 2009 CONN. PUB. ACTS NO. 09-5, *et seq.*

170. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

171. This is a civil action brought by Relators on behalf of the State of Connecticut against Defendants under the Connecticut False Claims Act, 2009 Conn. Pub. Acts No. 09-5.

172. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, presented, or caused to be presented to, and may still be presenting or causing to be presented to, an officer or employee of the State of Connecticut or its political subdivisions false or fraudulent claims for payment, in violation of 2009 Conn. Pub. Acts No. 09-5 § 2(a)(1).

173. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid in violation of Conn. Pub. Acts No. 09-5 § 2(a)(2).

174. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Connecticut or its political subdivisions in violation of Conn. Pub. Acts No. 09-5 § 2(a)(1).

175. The State of Connecticut, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state and state subdivision funded health insurance programs.

176. As a result of Defendants' actions as set forth above, the State of Connecticut, including its political subdivisions, has been, and may continue to be, severely damaged.

COUNT VII
VIOLATION OF THE STATE OF DELAWARE FALSE CLAIMS AND REPORTING ACT, DEL. CODE ANN. TIT. 6 § 1201, *et seq.*

177. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

178. This is a civil action brought on behalf of Relators on behalf of the Government of the State of Delaware against Defendants under the State of Delaware's False Claims and Reporting Act, DEL. CODE ANN. tit. 6, § 1203(b).

179. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, directly or indirectly, to an officer or employee of the Government of the State of Delaware false or fraudulent claims for payment or approval, in violation of DEL. CODE ANN. tit. 6, §1201 (a)(1).

180. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved, in violation of DEL. CODE ANN. tit. 6, §1201(a)(2).

181. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or

quantity than is due or when no benefit or payment is authorized, in violation of DEL. CODE ANN. tit. 6, §1201(a)(3).

182. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, increase or decrease an obligation to pay or transmit money to the Government of Delaware, in violation of DEL. CODE ANN. tit. 6, § 120l(a)(7).

183. The Government of the State of Delaware, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health care programs funded by the Government of the State of Delaware.

184. As a result of Defendants' actions, the Government of the State of Delaware has been, and may continue to be, severely damaged.

COUNT VIII
VIOLATION OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT, D.C. CODE A § 2-308.13, *et seq.*

185. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

186. This is a civil action brought by Relators, in the name of the District of Columbia against Defendants under the District of Columbia False Claims Act, D.C. CODE ANN. § 2-308.15(a).

187. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the District, a false or fraudulent claim for payment or approval, in violation of D.C. CODE ANN. § 2-308.14(a)(l).

188. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly used or caused to be used, and may continue to use or cause to be used, false records and/or statements to get false claims paid or approved by the District, in violation of D.C. CODE ANN. § 2-308.14(a)(2).

189. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of D.C. CODE ANN. § 2-308.14(a)(3).

190. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or used, or caused to be made or used, and may still be making or using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the District, in violation of D.C. CODE ANN. § 2-308.14(a)(7).

191. The District of Columbia, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid,

and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the District.

192. As a result of Defendants' actions, as set forth above, the District of Columbia has been, and continues to be, severely damaged.

COUNT IX
VIOLATION OF THE STATE OF FLORIDA
FALSE CLAIMS ACT, FLA. STAT. 68-081, *et seq.*

193. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

194. This is a civil action brought by Relators on behalf of the State of Florida against Defendants under the State of Florida's False Claims Act, FLA. STAT. ANN. § 68.083(2).

195. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Florida or one of its agencies false or fraudulent claims for payment or approval, in violation of FLA. STAT. ANN. § 68.082(2)(a).

196. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082(2)(b).

197. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose,

an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of FLA. STAT. ANN. § 68.082(2)(c).

198. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Florida or one of its agencies, in violation of FLA. STAT. ANN. § 68.082 (2)(g).

199. The State of Florida and its agencies, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance plans funded by the State of Florida or its agencies.

200. As a result of Defendants' actions, as set forth above, the State of Florida and/or its agencies have been, and may continue to be, severely damaged.

COUNT X
VIOLATION OF STATE OF GEORGIA MEDICAID FALSE CLAIMS ACT, GA. CODE ANN. § 49-4-168 (2007), *et seq.*

201. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

202. This is a civil action brought by Relators, in the name of the State of Georgia, against Defendants pursuant to the State of Georgia Medicaid Fraud False Claims Act, GA. CODE ANN. § 49-4-168 (2007), *et seq.*

203. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Georgia Medicaid program, in violation of GA. CODE ANN. § 49-4-168.1(a)(1) (2007).

204. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of GA. CODE ANN. § 49-4-168.1(a)(2) (2007).

205. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of GA. CODE ANN. § 49-4-168.1(a)(3) (2007).

206. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was

made, in whole or in part, under the Medicaid program, in violation of GA. CODE ANN. § 49-4-168.1(a)(7) (2007).

207. The State of Georgia or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

208. As a result of Defendants' actions, as set forth above, the State of Georgia or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XI
VIOLATION OF THE STATE OF HAWAII FALSE CLAIMS ACT
FALSE CLAIMS TO THE STATE,
HAWS REV. STAT. § 661-21, *et seq.*

209. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

210. This is a civil action brought by Relators on behalf of the State of Hawaii and its political subdivisions against Defendants under the State of Hawaii's False Claims Act -False Claims to the State, HAW. REV. STAT. § 661-25.

211. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to officers or employees of the State of Hawaii, or its political subdivisions, false or fraudulent claims for payment or approval, in violation of HAW. REV. STAT. § 61-21(a)(l).

212. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made and used, and may still be making, using or causing to be made

or used, false records or statements to get false or fraudulent claims paid or approved by the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(2).

213. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of HAW. REV. STAT. § 661-21(a)(3).

214. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Hawaii, or its political subdivisions, in violation of HAW. REV. STAT. § 661-21(a)(7).

215. The State of Hawaii, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

216. As a result of Defendants' actions, as set forth above, the State of Hawaii and/or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XII
VIOLATION OF THE STATE OF ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT, 740 ILL. COMP. STAT. ANN. 175/1, *et seq.*

217. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

218. This is a civil action brought by Relators on behalf of the State of Illinois against Defendants under the State of Illinois Whistleblower Reward and Protection Act, 740 ILL, COMP. STAT. ANN. 175/4(b).

219. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the State of Illinois or a member of the Illinois National Guard a false or fraudulent claim for payment or approval, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(1).

220. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(2).

221. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(3).

222. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Illinois, in violation of 740 ILL. COMP. STAT. ANN. 175/3(a)(7).

223. The State of Illinois, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

224. As a result of Defendants' actions, as set forth above, the State of Illinois has been, and may continue to be, severely damaged.

COUNT XIII
VIOLATION OF THE STATE OF INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT, IND. CODE § 5-11-5.5, *et seq.*

225. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

226. This is a civil action brought by Relators on behalf of the State of Indiana against Defendants under the State of Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-4(a).

227. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally presented, or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(l).

228. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain payment or approval of false claims by the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(b)(2).

229. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of IND. CODE ANN. § 5-11-5.5-2(a)(3).

230. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, false records or statements to avoid an obligation to pay or transmit money to the State of Indiana, in violation of IND. CODE ANN. § 5-11-5.5-2(a)(6).

231. The State of Indiana, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of those claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

232. As a result of Defendants' actions, as set forth above, the State of Indiana has been, and may continue to be, severely damaged.

COUNT XIV
VIOLATION OF THE STATE OF LOUISIANA

MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW, LA. REV. STAT. § 46:437.1, *et seq.*

233. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

234. This is a civil action brought by Plaintiff, Relators, on behalf of the State of Louisiana's medical assistance programs against Defendants under the State of Louisiana Medical Assistance Programs Integrity Law, LA. REV. STAT. § 46:439.1.

235. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may still be presenting or causing to be presented, false or fraudulent claims, in violation of LA. REV. STAT. § 46:438.3(A).

236. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly engaged in misrepresentation, and may still be engaging in misrepresentation, to obtain, or attempt to obtain, payment from medical assistance programs funds, in violation of LA. REV. STAT. § 46:438.3(B).

237. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment cither in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of LA. REV. STAT, § 46:438.3 (C).

238. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

submitted, and may continue to submit, claims for goods, services or supplies which were medically unnecessary or which were of substandard quality or quantity, in violation of LA. REV. STAT, § 46:438.3 (D).

239. The State of Louisiana, its medical assistance programs, political subdivisions and/or the Department, unaware of the falsity of the claims and/or statements made by Defendants, or their actions as set forth above, acted in reliance, and may continue to act in reliance, on the accuracy of Defendants' claims and/or statements in paying for prescription drugs and prescription drug-related management services for medical assistance program recipients.

240. As a result of Defendants' actions, the State of Louisiana, its medical assistance programs, political subdivisions and/or the Department have been, and may continue to be, severely damaged.

COUNT XV
VIOLATION OF THE COMMONWEALTH OF MASSACHUSETTS FALSE CLAIMS ACT, MASS LAWS ANN. Ch. 12, § 5A, *et seq.*

241. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

242. This is a civil action brought by Relators on behalf of the Commonwealth of Massachusetts against Defendants under the Massachusetts False Claims Act, MASS. LAWS ANN. ch. 12, § 5C(2).

243. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MASS. LAWS ANN, ch. 12, § 5B(1).

244. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth of Massachusetts or its political subdivisions in violation of MASS. LAWS ANN. ch. 12, § 5B(2).

245. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of MASS. LAWS ANN. ch. 12, § 5B(3).

246. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth of Massachusetts or one of its political subdivisions, in violation of MASS. LAWS ANN. ch. 12, § 5B(8).

247. The Commonwealth of Massachusetts, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

248. As a result of Defendants' actions, as set forth above, the Commonwealth of Massachusetts or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVI
VIOLATION OF THE STATE OF MICHIGAN MEDICAID FALSE CLAIMS ACT,
MICH. COMP. LAWS SERV. § 400.601, *et seq.*

249. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

250. This is a civil action brought by Relators in the name of the State of Michigan against Defendants under the State of Michigan Medicaid False Claims Act, MICH. COMP. LAWS SERV. § 400.610a(l).

251. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or caused to be made, and may still be making or causing to be made, a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of MICH. COMP. LAWS. SERV. § 400.603(1).

252. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made or cause to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit, in violation of MICH. COMP. LAWS. SERV. § 400.603(2).

253. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly concealed or failed to disclose, and may still be concealing or failing to disclose, an event affecting its initial or continued right to receive a Medicaid benefit or the initial or continued

right of any other person on whose behalf Defendants has applied for or is receiving a benefit with intent to obtain a benefit to which Defendants are not entitled or in an amount greater than that to which Defendants are entitled, in violation of MICH. COMP. LAWS. SERV. § 400.603(3).

254. Defendants, in possession of facts under which they are aware or should be aware of the nature of their conduct and that their conduct is substantially certain to cause the payment of a Medicaid benefit, knowingly presented or made or caused to be presented or made, and may still be presenting or causing to be presented a false claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, in violation of MICH. COMP. LAWS. SERV. § 400.607(1).

255. The State of Michigan, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

256. As a result of Defendants' actions, as set forth above, the State of Michigan or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVII
VIOLATION OF THE STATE OF MINNESOTA FALSE CLAIMS ACT, MINN. STAT. § 15C.01

257. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

258. This is a civil action brought by Relators on behalf of the State of Minnesota against Defendants under the State of Minnesota False Claims Act, Minn. Stat. § 15C.01.

259. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of Minn. Stat. § 15C.02(a)(1).

260. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of Minn. Stat. § 15C.02(a)(2).

261. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Minnesota or one of its political subdivisions, in violation of Minn. Stat. § 15C.02(a)(7).

262. The State of Minnesota, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

263. As a result of Defendants' actions, as set forth above, the State of Minnesota or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XVIII
VIOLATION OF STATE OF MONTANA FALSE CLAIMS ACT, MONT. CODE ANN. § 17-8-401, *et seq.*

264. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

265. This is a civil action brought by Relators on behalf of the State of Montana against Defendants under the State of Montana False Claims Act, MONT. CODE ANN. § 17-8-406(1).

266. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of MONT. CODE ANN. § 17-8-403(l)(a).

267. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of MONT. CODE ANN. § 17-8-403(1)(b).

268. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment cither in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of MONT. CODE ANN. § 17-8-403(l)(c).

269. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Montana or one of its political subdivisions, in violation of MONT. CODE ANN. § 17-8-403(l)(g).

270. The State of Montana, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

271. As a result of Defendants' actions, as set forth above, the State of Montana or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XIX
VIOLATION OF THE STATE OF NEVADA
SUBMISSION OF FALSE CLAIMS TO STATE OR LOCAL
GOVERNMENT ACT, NEV. REV. STAT. ANN. § 357.010, *et seq.*

272. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

273. This is a civil action brought by Relators on behalf of the State of Nevada against Defendants under the State of Nevada Submission of False Claims to State or Local Government Act, NEV. REV. STAT. ANN. § 357.080(1)

274. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of NEV. REV. STAT. ANN. § 357.040(l)(a).

275. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to obtain payment or approval for false claims in violation of NEV. REV. STAT. ANN. § 357.040(1)(b).

276. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment cither in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of NEV. REV. STAT. ANN. § 357.040(1)(c).

277. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of Nevada or one of its political subdivisions, in violation of NEV. REV. STAT. ANN. § 357.040(1)(g).

278. The State of Nevada, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-

related management services for recipients of health insurance programs funded by the state or its political subdivisions.

279. As a result of Defendants' actions, as set forth above, the State of Nevada or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XX
VIOLATION OF STATE OF NEW HAMPSHIRE MEDICAID FALSE CLAIMS ACT, N.H. REV. STAT. ANN. § 167:61-b, *et. seq.*

280. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

281. This is a civil action brought by Relators on behalf of the State of New Hampshire against Defendants under the State of New Hampshire Medicaid False Claims Act, N.H. REV. STAT. ANN. § 167:61-cII.(a).

282. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(a).

283. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a fake claim paid or approved, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(b).

284. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose,

an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(c).

285. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Hampshire or one of its political subdivisions, in violation of N.H. REV. STAT. ANN. § 167:61-bI.(e).

286. The State of New Hampshire, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

287. As a result of Defendants' actions, the State of New Hampshire or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXI
VIOLATION OF STATE OF NEW JERSEY
FALSE CLAIMS ACT, N.J. STAT. ANN. § 265 (2007), *et seq.*

288. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

289. This is a civil action brought by Relators, in the name of the State of New Jersey, against Defendants pursuant to the State of New Jersey Fraud False Claims Act, N.J. STAT. ANN. § 265 (2007), *et seq.*

290. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the New Jersey Medicaid program, in violation of N.J. STAT. ANN. § 265 (3)(a) (2007).

291. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of N.J. STAT. ANN. § 265 (3)(b) (2007).

292. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of N.J. STAT. ANN. § 265 (3)(c) (2007).

293. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of N.J. STAT. ANN. § 265 (3)(g) (2007).

294. The State of New Jersey or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

295. As a result of Defendants' actions, as set forth above, the State of New Jersey or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXII
VIOLATION OF STATE OF NEW MEXICO MEDICAID FALSE CLAIMS ACT, N.M STAT. ANN. § 27-14-1, *et seq.*

296. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

297. This is a civil action brought by Relators on behalf of the State of New Mexico against Defendants under the State of New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-14-7(B).

298. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false or fraudulent claim for payment under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4A.

299. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented, or caused to be presented, and may be continuing to present or causing to be presented a claim for payment under the Medicaid program that is not authorized or is not eligible for benefit under the Medicaid program, in violation of N.M. STAT. ANN. § 27-14-4B.

300. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of N.M. STAT. ANN. § 27-14-4C.

301. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New Mexico or one of its political subdivisions, in violation of N.M. STAT. ANN. § 27-14-4E.

302. The State of New Mexico, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

303. As a result of Defendants' actions, as set forth above, the State of New Mexico or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIII
VIOLATION OF THE STATE OF NEW YORK FALSE CLAIMS ACT, N.Y. CLS. ST. FIN. § 187 *et seq.*

304. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

305. This is a civil action brought by Relators on behalf of the State of New York against Defendants under the State of New York False Claims Act, N.Y. CLS St. Fin. § 190.2.

306. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, a false claim for payment or approval, in violation of N.Y. CLS St. Fin. § 189(a).

307. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get a false claim paid or approved, in violation of N.Y. CLS St. Fin. § 189(b).

308. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of N.Y.CLS St. Fin. § 189(c).

309. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of New York or one of its political subdivisions, in violation of N.Y.CLS St. Fin. § 189(g).

310. The State of New York, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

311. As a result of Defendants' actions, as set forth above, the State of New York or its political subdivisions have been, and may continue to be, severely damaged.

COUNT XXIV
VIOLATION OF THE STATE OF NORTH CAROLINA
FALSE CLAIMS ACT, N.C. GEN. STAT. § 1-605, *et seq.*

312. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

313. This is a civil action brought by Relators on behalf of the State of North Carolina against Defendants under the North Carolina False Claims Act, N.C. GEN. STAT. § 1-605.

314. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented a false claim for payment or approval, in violation of N.C. GEN. STAT. § 1-607(a)(1).

315. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used false records or statements to obtain payment or approval of claims by the State of North Carolina or its political subdivisions in violation of N.C. GEN. STAT. § 1-607(a)(2).

316. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the State of North Carolina or one of its political subdivisions, in violation of N.C. GEN. STAT. § 1-607(a)(7).

317. The State of North Carolina, or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid for prescription drugs and prescription drug-related management services for recipients of health insurance programs funded by the state or its political subdivisions.

318. As a result of Defendants' actions, as set forth above, the State of North Carolina or its political subdivisions have been severely damaged.

COUNT XXV
VIOLATION OF STATE OF OKLAHOMA MEDICAID
FALSE CLAIMS ACT, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*

319. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

320. This is a civil action brought by Relators, in the name of the State of Oklahoma, against Defendants pursuant to the State of Oklahoma Medicaid Fraud False Claims Act, OKLA. STAT. tit. 63, § 5053 (2007), *et seq.*

321. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment

under the Oklahoma Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2)(a) (2007).

322. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of OKLA. STAT. tit. 63, § 5053 (2)(b) (2007).

323. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of OKLA. STAT. tit. 63, § 5053 (2)(c) (2007).

324. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of OKLA. STAT. tit. 63, § 5053 (2)(g) (2007).

325. The State of Oklahoma or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims

and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

326. As a result of Defendants' actions, as set forth above, the State of Oklahoma or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXVI
VIOLATION OF STATE OF RHODE ISLAND
FALSE CLAIMS ACT, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*

327. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

328. This is a civil action brought by Relators, in the name of the State of Rhode Island, against Defendants pursuant to the State of Rhode Island Fraud False Claims Act, R.I. GEN. LAWS § 9-1.1-1 (2008), *et seq.*

329. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for any benefit or payment under the Rhode Island Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-3 (1) (2008).

330. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or representation of material fact for use in determining rights to a benefit or payment, in violation of R.I. GEN. LAWS § 9-1.1-3 (2) (2008).

331. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of R.I. GEN. LAWS § 9-1.1-3 (3) (2008).

332. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly offered or paid, and may still be offering or paying, remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for purchasing, ordering or arranging for, or recommending purchasing or ordering of, a good, supply or service for which payment was made, in whole or in part, under the Medicaid program, in violation of R.I. GEN. LAWS § 9-1.1-3 (7) (2008).

333. The State of Rhode Island or its political subdivisions, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

334. As a result of Defendants' actions, as set forth above, the State of Rhode Island or its political subdivisions has been, and may continue to be, severely damaged.

COUNT XXVII
VIOLATION OF THE STATE OF TENNESSEE MEDICAID FALSE CLAIMS ACT, TENN. CODE *ANN.* § 71-5-181 *et seq.*

335. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

336. This is a civil action brought by Relators in the name of the State of Tennessee against Defendants under the Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 71-5-183(a).

337. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to the State of Tennessee a claim for payment under the Medicaid program knowing it was false or fraudulent, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(A).

338. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used or caused to be made or used, and may still be making, using or causing to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the State of Tennessee with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(B).

339. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of TENN. CODE ANN. § 71-5-182(a)(l)(C).

340. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made

or used, records or statements to conceal, avoid or decrease an obligation to pay or transmit money to the State of Tennessee, relative to the Medicaid program, with knowledge that such records or statements were false, in violation of TENN. CODE ANN. § 71-5-182(a)(1)(D).

341. The State of Tennessee, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of the Medicaid program.

342. As a result of Defendants' actions, as set forth above, the State of Tennessee has been, and may continue to be, severely damaged.

COUNT XXVIII
VIOLATION OF THE STATE OF TEXAS HUMAN RESOURCES CODE, TEX. HUM. RES. CODE § 36.001 *et seq.*

343. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

344. This is a civil action brought by Relators in the name of the State of Texas against Defendants under the State of Texas Human Resources Code, Medicaid Fraud Prevention Chapter, TEX. HUM. RES. CODE § 36.101(a).

345. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact on an application for a contract, benefit or payment under a Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(1).

346. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

or intentionally made or caused to be made, and may still be making or causing to be made, a false statement or misrepresentation of material fact that is intended to be used, and has been used, to determine a person's eligibility for a benefit or payment under the Medicaid program, in violation of TEX. HUM. RES. CODE § 36.002(2).

347. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made, caused to be made, induced or sought to induce, and may still be making, causing to be made, inducing or seeking to induce, the making of a false statement or misrepresentation of material fact concerning information required to be provided by a federal or state law, rule, regulation or provider agreement pertaining to the Medicaid program in violation of TEX. HUM. RES. CODE § 36.002(4)(B).

348. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally made a claim under the Medicaid program for a service or product that was inappropriate, in violation of TEX. HUM. RES. CODE § 36.002(7)(C),

349. The State of Texas, its political subdivisions or the Department, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of Medicaid.

350. As a result of Defendants' actions, as set forth above, the State of Texas, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXIX
VIOLATION OF THE COMMONWEALTH OF VIRGINIA FRAUD AGAINST TAXPAYERS ACT, VA CODE ANN. § 8.01-216.1, *et seq.*

351. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

352. This is a civil action brought by Relators on behalf of the Commonwealth of Virginia against Defendants under the Commonwealth of Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.5, *et seq.*

353. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to an officer or employee of the Commonwealth, a false or fraudulent claim for payment or approval, in violation of VA. CODE ANN. § 8.01-216.3(A)(l).

354. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(2).

355. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment cither in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of VA. CODE ANN. § 8.01-216.3(A)(3).

356. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly

made, used or caused to be made or used, and may still be making, using or causing to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money to the Commonwealth, in violation of VA. CODE ANN. § 8.01-216.3(A)(7).

357. The Commonwealth of Virginia, unaware of the falsity of the claims and/or statements made by Defendants, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

358. As a result of Defendants' actions, as set forth above, the Commonwealth of Virginia, its political subdivisions or the Department has been, and may continue to be, severely damaged.

COUNT XXX
VIOLATION OF THE State of Wisconsin
False Claims for Medical Assistance, WIS. STAT. § 20.931 (2007), *et seq.*;

359. Relators incorporate herein by reference the preceding paragraphs of the First Amended Complaint as though fully set forth herein.

360. This is a civil action brought by Relators on behalf of the State of Wisconsin against Defendant under the State of Wisconsin False Claims for Medical Assistance, WIS. STAT. § 20.931 (2007), *et seq.*;

361. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly presented or caused to be presented, and may still be presenting or causing to be presented, to any officer, or employee, or agent of the state, a false or fraudulent claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(a) (2007).

362. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to obtain approval or payment of a false claim for medical assistance, in violation of WIS. STAT. § 20.931(2)(b).

363. Defendants, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly or intentionally concealed or failed to disclose, and may still be concealing or failing to disclose, an event with an intent fraudulently to secure the benefit or payment either in a greater amount or quantity than is due or when no benefit or payment is authorized, in violation of WIS. STAT. § 20.931(2)(c).

364. Defendant, in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, or with actual knowledge of the falsity of the information, knowingly conspired, and may still be conspiring, to defraud the state by obtaining allowance or payment of a false claim for medical assistance; or knowingly made, used, or caused to be made or used, and may still be making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Medical Assistance program, in violation of WIS. STAT. § 20.931(2)(g).

365. The State of Wisconsin, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance upon the accuracy of these claims and/or statements, paid, and may continue to pay, for prescription drugs and prescription drug-related management services for recipients of state funded health insurance programs.

366. As a result of Defendant' actions, as set forth above, the State of Wisconsin, its political subdivisions or the Department has been, and may continue to be, severely damaged.

WHEREFORE, Relators pray for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729, *et seq.*; CAL. CODE § 12650, *et seq.*, COLO. REV. STAT. § 25.5-4-304 et seq., 2009 Conn. Pub. Acts No. 09-5, *et seq.*, DEL. CODE ANN. tit. 6, § 1201, *et seq.*, D.C. CODE ANN. § 2-308.13, *et seq.*, FLA. STAT. ANN. § 68.081, *et seq.*, GA. CODE ANN. § 49-4-168, *et seq.*, HAW. REV. STAT. § 661-21, *et seq.*, 740 ILL. COMP. STAT. ANN. § 1751, *et seq.*, IND. CODE ANN. § 5-11-5.5, *et seq.*, LA. REV. STAT. § 437.1, *et seq.*, MASS. LAWS ANN. Ch. 12, §5A, *et seq.*, MICH. COMP. LAWS SERV. § 400.601, *et seq.*, MINN. STAT. § 15C.01 et seq., MONT. CODE ANN. § 17-8-401, *et seq.*, NEV. REV. STAT. ANN. § 357.010, *et seq.*, N.H. REV. STAT. ANN. § 167:61-b, *et seq.*, N.J. STAT ANN. § 265, *et seq.*, N.M. STAT. ANN. § 27-14-1, *et seq.*, N.Y. CLS ST. FIN. § 187, *et seq.*, N.C. GEN. STAT. § 1-605, *et. seq.,* OKLA. STAT. tit. 63, § 5053, *et seq.*, R.I. GEN. LAWS § 9-1,1-1, *et seq.*, TENN. CODE ANN. § 71-5-181, *et seq.*, TEX. HUM. RES. CODE § 36.001, *et seq.*, VA. CODE ANN. § 8.01-216.1, *et seq.,* and WIS. STAT. § 20.931 (2007), *et seq.*

B. That judgment be entered in Relators' favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses

resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d), CAL. CODE § 12652(g), COLO. REV. STAT. § 25.5-4-306(4), 2009 Conn. Pub. Acts No. 09-5 § 5 (e), DEL. CODE ANN. tit. 6, § 1205, D.C. CODE ANN. § 2-308.15(f), FLA. STAT. ANN. § 68.085, GA. CODE ANN. § 49-4-168, HAW. REV. STAT. § 661-27, 740 ILL. COMP. STAT. ANN. 175/4(d), IND. CODE ANN. § 5-11-5.5-6(a), LA. REV. STAT. § 439.4, MASS. GEN. LAWS ch. 12, § 5F, MICH. COMP. LAWS SERV. § 400.610a(9), MINN. STAT. § 15C.13, MONT. CODE ANN. § 17-8-410, NEV. REV. STAT. ANN. § 357.220, N.H. REV. STAT. ANN. § 167:61-e, N.J. STAT ANN. § 265, N.M. STAT. ANN. § 27-14-9, N.Y. CLS St. Fin. § 190.6., N.C. GEN. STAT. § 1-607(a), OKLA. STAT. tit. 63, § 5053, R.I. GEN. LAWS § 9-1,1-1, TENN. CODE ANN. § 71-5-183, TEX. HUM. RES. CODE § 36.110, VA. CODE ANN. § 8.01-216.7, and WIS. STAT. § 20.931.

D. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of California or its political subdivisions multiplied as provided for in CAL. CODE § 12651(a), plus a civil penalty of no more than ten thousand dollars ($10,000) per claim as provided by CAL. CODE § 12651(a), to the extent such multiplied penalties shall fairly compensate the State of California or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

E. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the Government of the State of Colorado multiplied as provided for in COLO. REV. STAT. § 25.5-4-305, plus a civil penalty of not less than

five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Colorado Medicaid False Claims Act to the extent such multiplied penalties shall fairly compensate the Government of the State of Colorado for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

F. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the Government of the State of Connecticut multiplied as provided for in 2009 Conn. Pub. Acts No. 09-5 § 2(b), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each act in violation of the State of Connecticut False Claims Act, as provided by Conn. Pub. Acts No. 09-5 § 2(b), to the extent such multiplied penalties shall fairly compensate the Government of the State of Connecticut for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

G. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the Government of the State of Delaware multiplied as provided for in DEL. CODE ANN. tit. 6, §1201(a), plus a civil penalty of not less than five thousand five-hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Delaware False Claims and Reporting Act, as provided by DEL. CODE ANN. tit. 6, § 1201(a), to the extent such multiplied penalties shall fairly compensate the Government of the State of Delaware for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

H. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the District of Columbia, multiplied as provided for in D.C. CODE ANN. § 2-308.14(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, and the costs of this civil action brought to recover such penalty and damages, as provided by D.C. CODE ANN. § 2-308.14(a), to the extent such multiplied penalties shall fairly compensate the District of Columbia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

I. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Florida or its agencies multiplied as provided for in FLA. STAT. ANN. § 68.082, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by FLA. STAT. ANN. § 68.082, to the extent such multiplied penalties shall fairly compensate the State of Florida or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

J. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Georgia or its political subdivisions multiplied as provided for in GA. CODE ANN. § 49-4-168, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent of the proceeds per claim as provided by GA. CODE ANN. § 49-4-168.2, to the extent such multiplied penalties shall fairly compensate the State of Georgia or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

K. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Hawaii, multiplied as provided for in HAW. REV. STAT. § 661-21(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by HAW. REV. STAT. § 661-21(a), to the extent such multiplied penalties shall fairly compensate the State of Hawaii for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

L. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Illinois, multiplied as provided for in 740 ILL. COMP. STAT, ANN. 175/3(a), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000), and the costs of this civil action brought to recover such damages and penalty, as provided by 740 ILL. COMP. STAT. ANN. 175/3(a), to the extent such multiplied penalties shall fairly compensate the State of Illinois for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

M. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Indiana, multiplied as provided for in IND. CODE ANN. § 5-11-5.5-2, plus a civil penalty of at least five thousand dollars ($5,000) as provided by IND. CODE ANN. § 5-11-5.5-2, to the extent such multiplied penalties shall fairly compensate the State of Indiana for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

N. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by Louisiana's medical assistance programs, multiplied as provided for

in LA. REV. STAT § 438.6(B)(2), plus a civil penalty of no more than ten thousand dollars ($10,000) per violation or an amount equal to three times the value of the illegal remuneration, whichever is greater, as provided for by LA. REV. STAT § 438.6(B)(I), plus up to ten thousand dollars ($10,000) for each false or fraudulent claim, misrepresentation, illegal remuneration, or other prohibited act, as provided by LA. REV. STAT § 438.6(C)(l)(a), plus payment of interest on the amount of the civil fines imposed pursuant to Subsection B of § 438.6 at the maximum legal rate provided by La. Civil Code Art. 2924 from the date the damage occurred to the date of repayment, as provided by LA. REV. STAT. § 438.6(C)(l)(b), to the extent such multiplied fines and penalties shall fairly compensate the State of Louisiana's medical assistance programs for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

O. That judgment be entered in Relators' favor and against Defendants for restitution to the Commonwealth of Massachusetts or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MASS. LAWS ANN. ch. 12, 65B, multiplied as provided for in MASS. LAWS ANN. ch. 12, § 5B, plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) for each false claim, pursuant to MASS. LAWS ANN, ch. 12, 5B, to the extent such multiplied penalties shall fairly compensate the Commonwealth of Massachusetts or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

P. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Michigan or its political subdivisions for the value of payments or benefits

provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MICH. COMP. LAWS SERV. §§ 400.603-400.606, 400.610b, in order to fairly compensate the State of Michigan or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Q. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the Government of the State of Minnesota multiplied as provided for in MINN. STAT. § 15C.02(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) for each act in violation of the State of Minnesota False Claims Act to the extent such multiplied penalties shall fairly compensate the Government of the State of Minnesota for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

R. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Montana or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in MONT. CODE ANN. § 17-8-403(2), multiplied as provided for in MONT. CODE ANN. § 17-8-403(2), plus a civil penalty of up to ten thousand dollars ($10,000) for each false claim, pursuant to MONT. CODE ANN. § 17-8-403(2), to the extent such multiplied penalties shall fairly compensate the State of Montana or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

S. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Nevada for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in NEV. REV. STAT. ANN. 357.040, multiplied as provided for in NEV. REV. STAT. ANN. § 357.040(1), plus a civil penalty of not less than two thousand dollars ($2,000) or more than ten thousand dollars ($10,000) for each act, pursuant to NEV. REV. STAT. ANN. § 357.040, to the extent such multiplied penalties shall fairly compensate the State of Nevada for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

T. That judgment be entered in Relators' favor and against Defendants for restitution to the State of New Hampshire or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.H. REV. STAT. ANN. § 167:6111, multiplied as provided for in N.H. REV. STAT. ANN. § 167:61II, plus a civil penalty of two thousand dollars ($2,000) for each false claim, pursuant to REV. STAT. ANN. § 167:6111, to the extent such multiplied penalties shall fairly compensate the State of New Hampshire or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

U. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of New Jersey or its political subdivisions multiplied as provided for in N.J. STAT. ANN. § 265, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by N.J. STAT. ANN. § 265, to the extent such multiplied penalties shall fairly compensate the State of New Jersey or its political

subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

V. That judgment be entered in Relators' favor and against Defendants for restitution to the State of New Mexico or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.M. STAT. ANN. § 27-14-4, multiplied as provided for in N.M. STAT. ANN. § 27-14-4, to the extent such multiplied penalties shall fairly compensate the State of New Mexico or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after fill discovery;

That judgment be entered in Relators' favor and against Defendants for restitution to the State of New York or its political subdivisions for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in N.Y. CLS St. Fin. § 189.1., multiplied as provided for in N.Y. CLS St. Fin. § 189.1., plus a civil penalty of not less than six thousand dollars ($6,000) or more than twelve thousand dollars ($12,000) for each false claim, pursuant to N.Y. CLS St. Fin. § 189.l., to the extent such multiplied penalties shall fairly compensate the State of New York or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

W. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of North Carolina or its agencies multiplied as provided for in N.C. GEN. STAT. § 1-607(a), plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) as provided by N.C. GEN. STAT. § 1-607(a), to the extent such multiplied penalties shall fairly compensate the State of

North Carolina or its agencies for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

X. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Oklahoma or its political subdivisions multiplied as provided for in OKLA. STAT. tit. 63, § 5053, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by OKLA. STAT. tit. 63, § 5053.4, to the extent such multiplied penalties shall fairly compensate the State of Oklahoma or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Y. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the State of Rhode Island or its political subdivisions multiplied as provided for in R.I. GEN. LAWS § 9-1,1-1, plus a civil penalty of not less than fifteen (15) percent or more than twenty five (25) percent per claim as provided by R.I. GEN. LAWS § 9-1,1-4, to the extent such multiplied penalties shall fairly compensate the State of Rhode Island or its political subdivisions for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

Z. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Tennessee for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in TENN. CODE ANN. § 71-5-182, multiplied as provided for in TENN. CODE ANN. § 71-5-182(a)(l), plus a civil penalty of not

less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) pursuant to TENN. CODE ANN. § 71-5-182(a)(l), to the extent such multiplied penalties shall fairly compensate the State of Tennessee for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

AA. That judgment be entered in Relators' favor and against Defendants for restitution to the State of Texas for the value of payments or benefits provided, directly or indirectly, as a result of Defendants' unlawful acts, as provided for in TEX. HUM. RES. CODE § 36.052(a)(l), multiplied as provided for in TEX. HUM. RES. CODE § 36.052(a)(4), the interest on the value of such payments or benefits at the prejudgment interest rate in effect on the day the payment or benefit was paid or received, for the period from the date the payment or benefit was paid or received to the date that restitution is made to the State of Texas, pursuant to TEX. HUM. RES. CODE § 36.052(a)(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than fifteen thousand dollars ($15,000) for each unlawful act committed that resulted in injury to an elderly or disabled person, and of not less than one thousand dollars ($1,000) or more than ten thousand dollars ($10,000) for each unlawful act committed that did not result in injury to an elderly or disabled person, pursuant to TEX. HUM. RES. CODE § 36.052(a)(3)(A) and (B), to the extent such multiplied penalties shall fairly compensate the State of Texas for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

BB. That judgment be entered in Relators' favor and against Defendants in the amount of the damages sustained by the Commonwealth of Virginia, multiplied as provided for in VA. CODE ANN. § 8.01-216.3(A), plus a civil penalty of not less than five thousand dollars ($5,000)

or more than ten thousand dollars ($10,000) as provided by VA. CODE ANN. § 8.01-216.3(A), to the extent such multiplied penalties shall fairly compensate the Commonwealth of Virginia for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

CC. That judgment be entered in Plaintiffs' favor and against Defendant in the amount of the damages sustained by the State of Wisconsin or its political subdivisions multiplied as provided for in WIS. STAT. § 20.931(2), plus a civil penalty of not less than five thousand dollars ($5,000) or more than ten thousand dollars ($10,000) as provided by WIS. STAT. § 20.931(2), to the extent such multiplied penalties shall fairly compensate the State of Wisconsin or its political subdivisions for losses resulting from the various schemes undertaken by Defendant, together with penalties for specific claims to be identified at trial after full discovery;

DD. That Defendants be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct; and

EE. That judgment be granted for Relators against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relator Lundstrom in the prosecution of this suit; and

FF. That Relators be granted such other and further relief as the Court deems just and proper.

WHEREFORE, Relators pray for judgment against Defendants as follows:

A. That Defendants be ordered to cease and desist from submitting any more false claims, or further violating 31 U.S.C. § 3729;

B. That judgment be entered in Relators' favor and against Defendants in the amount of each and every false or fraudulent claim, multiplied as provided for in 31 U.S.C. § 3729(a),

plus a civil penalty of not less than five thousand five hundred dollars ($5,500) or more than eleven thousand dollars ($11,000) per claim as provided by 31 U.S.C. § 3729(a), to the extent such multiplied penalties shall fairly compensate the United States of America for losses resulting from the various schemes undertaken by Defendants, together with penalties for specific claims to be identified at trial after full discovery;

C. That Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and § 3730(h), and all State *Qui Tam* statutes;

D. That judgment be granted for Relators to compensate for Defendants' unlawful retaliation against him for his whistleblowing activities;

E. That Relators be awarded compensatory and punitive damages to compensate him for his embarrassment and emotional distress;

F. That judgment be granted for Relators against Defendants for all costs, including, but not limited to, court costs, expert fees and all attorneys' fees incurred by Relators in the prosecution of this suit; and

G. That Relators be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Relators demand a trial by jury of all issues so triable.

Dated: September 21, 2010

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